P.A.C. No. 476

PUBLIC ACCOUNTS COMMITTEE
(1975-76)

(FIFTH LOK SABHA)

HUNDRED AND SEVENTY-NINTH REPORT

PRODUCTION OF POLIO VIRUS VACCINE

MINISTRY OF HEALTH & FAMILY PLANNING
(DEPARTMENT OF HEALTH)

[Paragraph 32 of the Report of the Comptroller & Auditor General of India for the year 1972-73, Union Government (Civil)]

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NEW DELHI

July, 1975/Sravana, 1897 (S)
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*Not printed. (One cyclostyled copy laid on the Table of the House and five copies placed in Parliament Library).

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Shri *H. G.* Paranjpe—Chief *Financial Committee Officer.*

Shri *N.* Sunder *Rajan—Senior Financial Committee Officer.*

INTRODUCTION

I, the Chairman of the Public Accounts Committee, as authorised by the Committee, do present on their behalf this Hundred and Seventy Ninth Report of the Public Accounts Committee (Fifth Lok Sabha) on paragraph **32** of the Report of the Comptroller and Auditor General of India for the year 1972-73, Union Government (Civil) relating to the Ministry of Health and Family planning (Department of Health) on the Production of Polio Virus Vaccine.

2. The Report of the Comptroller and Auditor General of India for the year 1972-73--Union Government (Civil) was laid on the Table of the House on the 30th April, 1974. The Committee (1974-75) examined the paragraph at their sitting held on the 20th August, 1974. The Committee (1975-76) considered and finalised this Report at their sitting held on the 18th July, 1975 based on the evidence taken and further information furnished by the Ministry of Health and Family Planning (Department of Health). Minutes of the sitting form Part 11* of the Report.

3. A statement containing the summary of the main conclusions/ recommendations of the Committee is appended to the Report (Appendix II). For facility of reference these have been printed in thick type in the body of the Report.

4. The Committee place on record their appreciation of the commendable work done by the Public Accounts Committee (1974-75) in taking evidence and obtaining information for this Report.

5. The Committee place on record their appreciation of the assistance rendered to them in the examination of the Audit Report by the Comptroller and Auditor General of India.

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6. The Committee would also like to express their thanks to the officers of the Ministry of Health and Family Planning (Department of Health) for the cooperation extended by them in giving information to the Committee.

NEW DELHI;
July 24, 1975.
Sravana 2, 1897 *(Saka).*

H. N. MUKERJEE,
Chairman,
Public *Accounts* Committee.

REPORT

MINISTRY OF HEALTH AND FAMILY PLANNING

(DEPARTMENT OF HEALTH)

Production of Polio Virus Vaccine

Audit Paragraph

1.1. Poliomyelitis is a disease of the central nervous system (brain, spinal cord and nerves). Children are more susceptible than adults to this disease. The disease is caused by a virus which enters the body through the mouth or the nose. It then reaches and affects certain nerve centres resulting in weakening or paralysis of certain muscles. How the disease spreads from one person to another is not definitely known, but the virus has been found in the nose, throat and bowel discharges of patients. Early symptoms of the disease are severe cold, influenza, fever, headache, vomitting, drowsiness etc.

1.2. No specific drug to cure polio has yet been discovered. A vaccine made from Sabin strains of the virus (named after the inventor Dr. A. B. Sabin) has been in use since 1959; this, according to medical experts, protects a high proportion of those to whom it is administered. The vaccine is a preparation of live attenuated poliovirus types I, II or III containing any one type or a combination of the three types (trivalent vaccine). Normally, three doses of trivalent vaccine (combination of types I, II and III of monovalent vaccine) are given at intervals of 4 to 6 weeks for satisfactory immunisation. It has been estimated that out of the population of 54.80 crores according to the 1971 census, 8.20 crore children are in the susceptible group for whom 24.60 crore doses of trivalent vaccine are needed annually. Besides, for the estimated 1.30 crore new borns, about 3.90 crore doses of trivalent vaccine are also required each year. There being no national programme for immunisation, the country's annual requirement has been presently estimated as 1.20 crore trivalent doses.

1.3. In November 1961 Government of India approved production (in the country) of polio virus vaccine (oral) with Sabin strains. Dr. A. B. Sabin visited India as a World Health Organisation consultant and recommended in January;February 1963 production of the vaccine at the Pasteur Institute at Coonoor. The buildings for the new laboratories for production of the vaccine were completed in

1964. Total expenditure on this project upto March, 1972 was Rs. 21.15 lakhs excluding foreign aid of Rs. 7.48 lakhs.

1.4. The Institute has a capacity to produce 12.50 lakh trivalent doses or 37.50 lakh monovalent doses a year. It started preparation of seed virus from August 1964. The specimens were sent for testing to Medical Research Council Laboratories, London, from October, 1965 onwards. Preparation of batches of bulk vaccine started in December 1966. Between December 1966 and May 1973, apart from 4.61 lakh doses of trivalent vaccine (equivalent to 13.83 lakh doses of monovalent vaccine) the Institute produced only 63.91 lakh doses of monovalent vaccine as shown below:

	Type I	Type II	Type III	Total
		(In lakhs)		
Approved for use	6.32	13·70	18·45	38·47
Awaiting approval or undergoing tests .	10·44	9·20	5·80	25·44
TOTAL .	16·76	22·90	24·25	63·91

1.5. For preparation and testing of polio vaccine imported African green monkeys, chemicals and equipment are necessary. The Director of the Institute stated (December 1972) that production had been less than the capacity as there was delay in getting imported monkeys, chemicals and equipment. For example, import licence for 12 monkeys (cost: Rs. 11.000) was applied for in March 1970 but was granted after 15 months in July 1971, and the monkeys were received in October 1971. Import licence for 12 more monkeys (cost: Rs. 11,000) was applied for in May 1973 and was granted in October 1973; thereafter due to non-availability of funds the monkeys could not be imported (January 1974). The Director of the Institute stated (January 1974) that there was delay in getting import licence as clearance was required from the Director General, Technical Development, State Trading Corporation etc., and it was difficult to impress on the administrative authorities that the monkeys were not available in India and were to be imported for tests in connection with preparation of live oral polio vaccine. Import licence for 9 A.C. motors (B.S. 170 Matburn) with internal resisters (cost: Rs. 4,747) applied for in June 1970, was granted in April 1972; the motors with internal resisters were received in September 1973. Besides, as trained workers were not available, new recruits had to be trained. Pre-

paration and testing of polio vaccine are highly sophisticated procedures. Depending on equipment and facilities available these have to be modified and at the same time standards have to be maintained. Training of staff in all the procedures takes time and is arduous. According to the Director of the Institute (January 1974), training of the staff in selected basic procedures was started soon after recruitment, and training of most of them, specially in the higher grades, was continuing in one or the other of the specialised procedures for preparation and testing of the vaccine.

1.6. Apart from a variety of tests conducted in the Institute as recommended by Dr. Sabin, the monovalent vaccines are tested finally by an independent agency. As facilities for this test were not available in the country, monovalent vaccines were being sent to foreign countries till December, 1969 for the final test (neurovirulence test); it was taking about 9 to 18 months to get the results of the tests. Even after this test approval of the Drug Controller is necessary for preparation of trivalent vaccine from the monovalent vaccines. According to the procedures recommended hy W.H.O.the Drug Controller is assisted by a Committee consisting of representatives of the Director General of Health Services, Drug Controller, the Institute which prepares the vaccine, the National Institute of Communicable Diseases etc. It took about 5 to 8 months to get this approval.

1.7. A polio vaccine testing division started functioning in the National Institute of Communicable Diseases, Delhi, in the latter part of 1970 for conducting neurovirulence test. Till March 1972, Rs. 14.45 lakhs were spent on the division (excluding cost of buildings but including foreign aid of Rs. 1.18 lakhs). Facilities are available in this division for testing not less than 160 lakh doses of trivalent polio vaccine per year. This division was ready in March 1971 for conducting neurovirulence test and received 8.67 lakh monovalent doses of types I and III from the Institute in May 1971 for which test reports were sent in May July. 1972. In March 1973 the Drug Controller approved production of trivalent doses from these monovalent doses and 19.350 trivalent doses were prepared in May, 1973. The next batch of 5.80 lakh monovalent doses was sent to the division for test in January. 1963. The Director of the Pasteur Institute stated (Januarv 1974) that no other batch was sent earlier as it was decided to send large volumes of bulk vaccine for neurovirulence test to save cost (which was high) of such test. The test-report on this batch of doses had not been sent by the testing division (June 1973). The Institute did not send the remaining monovalent doses for neurovirulence test as preliminary test conducted at the Institute indicated that some of the batches of vaccine had lower virus content. According to the Institute (June 1973), this was attributable to the reduced

sensitivity of the monkey kidney cultures used for virus titrations at the Institute. The Director of the Institute stated that the reasons for the reduced sensitivity of the monkey kidney cultures used by the Institute were under study and that attempts were being made to increase the sensitivity of the method of titration.

1.8. Although the Institute had a stock of 38.47 lakh approved monovalent doses in May 1973, only 6.32 lakh trivalent doses can be prepared as only that number of doses of monovalent type I was available. The Institute stated (June 1973) that type I was produced less as it is more difficult to produce than the other two types. Only 1.10 lakh trivalent doses out of 4.61 lakh doses already produced had been distributed for use (May 1973). The Director of the Institute stated in February 1973 that production of trivalent vaccines was dependent on prompt distribution and sale of polio vaccine. It was decided in June 1971 in a meeting presided over by the Director General of Health Services that trivalent vaccines would be distributed through the Medical Stores, Depot, Madras Distribution of the trivalent vaccine through that Depot was, however, started in August 1973. The Director of the Institute stated (January 1974) that there was delay in marketing the vaccine as the Depot had to be equipped with deepfreeze, air conditioner etc. for storage of the vaccine. He also stated that some time was taken in fixing the price of the vaccine and arranging details of its distribution (the vaccine is to be stored at —20° C and transported in dry ice). In the meantime, date of expiry (18 months from the date of the last satisfactory potency test) of 0.60 lakh doses was over in July 1972/August 1972. The Director of the Institute stated (January 1974) that these doses had been reitarated and period of their usuability had been extended by the Drug Controller up to April, 1975.

1.9. As the Institute could not meet the requirement of the country. polio vaccines had to be imported as shown below:—

Year	Number of doses (in lakhs	Value (in lakhs of rupees)
1966	6·53	1·08
1967	23·00	2·69
1968	6·19	0·91
1969	18·29	1·90
1970	23·74	2·53
1971	62·33	7·57
1972	79·52	10.00

1.10. It will appear from the above that the number of doses available in the country (imported plus indigenously produced) has been less than the estimated annual requirement of 1.20 crore doses. The Director of the Institute stated (January 1974) that "it is a well known fact that as the epidemic declines the public lose their enthusiasm for immunizing the children and fail to give the 3 doses necessary to each child to ensure proper immunization. This may account for the lesser number of doses actually imported."

1.11. Imported vaccine costs about 15 paise while cost of nroduction by the Institute is about 50 paise per dose.

[Paragraph 32 of the Report of the Comptroller and Auditor General of India for the year 1972-73, Union Government (Civil)].

General Background

1.12. A note on poliomyelitis and its control, furnished to the Committee by the Ministry of Health and Family Planning (Department of Health), is reproduced below:

"Poliomyelitis is an acute infectious disease, primarily of children, which affects the central nervous system and occurs both sporadically and epidemically. The aegiological agent has been identified as an enterovirus—known as the poliovirus—with three distinct antigenic serotypes, type 1, 2 and 3. The virus is rapidly inactivated by heat, desiccation, formalin, chlorine and ultra-violet irradiation.

The incubation period, on an average is 17 days and the infection spreads through faecal to oral route. There are no non-human reservoirs for poliomyelitis. It is primarily an infection of elementary tract with the virus multiplying in the regional lymph nodes. There is no clinical evidence of infection unless the virus, after multiplying in the regional lymph nodes passes into the blood system and localises in the central nervous system. The laboratory investigations are suggestive that only a small percentage

of infected persons suffer from a clinical disease and in only a minority of these there is paralysis or meningo—encephalitis.

The laboratory diagnosis of poliomyelitis in a patient with an atypical clinical picture can be established by virus isolation from stool and demonstration of an increasing antibody level in acute and convalescent phase sera. There is no specific treatment for the paralysis produced by poliovirus. In addition to the general supportive measures that are recommended in any acute infectious disease, Physiotherapy, must be initiated in the affected limbs immediately. Prophylactically, quarantine of contacts is nut recommended and during an epidemic in addition to mass immunization the general protective and sanitary measures must be taken. Both overcrowding and surgical operations must be avoided during the epidemic. It goes without saying that physiotherapy is of vital importance in acute and convalescent phases and must not be ignored under any circumstances.

Oral polivaccine is most valuable as a prophylactic agent: It has no curative value. The vaccine may be administered to any one including infants at about 3—6 months of age. The only contra-indications for the administration of the vaccine are acute infectious diseases, high fever, vomitting and dysentery. Patients suffering from acute leukemia and lymphoma, generalised malignancy and receiving corticosteroides, antimetabolites may not be given the oral poliovaccines. One should avoid breastfeeding at least 4—6 hours before and 4—6 hours after the administration of the vaccine. Although there is no contra-indication to the use of multiple vaccines on the same day, no other immunizing agent other than the oral poliovaccine be administered on a particular day. All the vaccines must be advised not to take hot water, hot milk or hot coffee for half-an-hour after the administration of the vaccine."

1.13. The following table indicates the number of cases and deaths due to poliomyelitis recorded in various States and Union Territories;

during the five year period from 1970 to 1974:

S. No.	Name of State/ Union Territory	1970		1971		1972		1973		1974		Reference period for 1974
		C	D	C	D	C	D	C	D	C	D	
1	Andhra Pradesh	7532	13	*120	1	737	12	625	23	38	5	Jan. 74
2	Gujarat	17	1	†	†	*84	=	72	=	69	=	Jan. to June.
3	Haryana	85	2	379	2	122	2	209	3	50	=	Jan. to May.
4	Himachal Pradesh.	3	=	155	=	†	†	†	†	†	†	
5	Jammu & Kashmir.	*8	=	†	†	†	†	†	†	†	†	
6	Kerala	*71	9	31	1	187	7	139	2	31	6	Jan.—June
7	Madhya Pradesh	148	10	374	7	280	7	462	12	69	=	Jan.—May.
8	Maharashtra	†	†	=	—	†	T	438	41	55	4	Jan.—June.
9	Mysore	77	2	679	2	@91	2	98	2	†	†	
10	Orissa		t	263	3	132*	2	41	=	18	—	Jan.—March & June.
11	Punjab	*26*	—	*86*	*1*	201	*2*	95	1	=	—	
12	Rajasthan	220	6	311	6	280	8	158	3	187	1	Jar-.—June
13	Tamil Nadu	33	13	65	22	294	10	195	*6*	†	†	
14	Tripura	†	†	†	†	†	†	51	—	†	†	
15	U.P.	†	†	18	—	†	†	†	†	†	†	
16	Arunachal Pradesh.	—	—	†	†	†	†	†	†	†	6	Jan.
17	Chandigarh	†	†	*59	1	3	—	4	—	28	—	Jan.—June.
18	Delhi	15	—	†	†	†	†	249	—	71	—	Jan.—April
19	Gna, Daman and Diu.	—	—	—	—	2	—	—	—	—	—	
20	L.M. and A. Islands.	—	—	1	—	t	t	—		—9	—	Jan.
21	Pondicherry	†	†	1	—	7	—	—	—	—	—	
	TOTAL	8235	58	2542	46	2420	52	2836	93	632	16	

Note : † Information not **available.**
— **Nil** information.
*Combined figures for Paralytic and Non-paralytic.
@ Figures are only for January to April.
C. **Cases.**
D. Deaths.

Source : Ministry of Health & **Family Planning** (Department of Health).

1.14. The Committee desired to know the effectiveness of oral vaccines for poliomyelitis in foreign countries and in India. The Director General, Health Services stated during evidence:

> 'You probably want to know about the prevalence of the disease in the country, as compared to other countries. It has been our observation that as the water supply of a country improves on the whole, the natural immunization which takes place among the population, does not take place. As such, the areas where there is more protected water supply, are the very areas which will become more susceptible to poliomyelitis. We have been keeping close track of the epidemics occurring in the country from 1971; there have been incidences numbering less than 700 at a time in some of the States. In Punjab there were 653 cases. Madhya Pradesh recorded 816 cases; but the disease did break out in epidemic form about six years back in the Godavari delta; and thereafter, we took precaution to see that the country should become self-sufficient with regard to the production of poliomyelitis vaccine; but as the health status and the water situation improved, as it has done in the Western countries, there is a greater possibility of infection spreading in the country."

1.15. Since polio amongst children appeared to be more in the States of Orissa and Rajasthan and also in and around Delhi, the Committee asked whether polio was more prevalent in the slum areas or in the urban areas and whether water from wells or from tanks was responsible for the disease. The witness stated:

> "Tap water is free from the virus of poliomyelitis but it is most dangerous to use water from hand-pumps. The water drawn from hand-pumps contains the virus and in various parts of the city the main source of water is from hand-pumps."

Explaining the reasons for the prevalence of polio in Delhi, the witness added that Delhi was one of the areas where hand-pumps were more in use.

1.16. The Committee enquired why no national programme for

immunisation against poliomyelitis had been contemplated. The Director General, ,Health Services, stated in evidence:

> "Only by supplying protected water to the whole country this disease can, to some extent, be eradicated. If that could be ensured, then there would be a National Programme. Otherwise there will be selective immunisation where children are susceptible."

He added in this connection:

> "This matter was discussed in several experts' meetings of the ICMR. In a few other meetings, the matter was discussed by me. The expert view is not to give protection to the whole child population but to concentrate on those areas where there are chances of outbreak. There is a proposal for a selective immunisation."

Subsequently, in a note furnished in this regard to the Committee, the Department of Health stated:

> "Polio is not endemic in all the States and Union Territories and it was only after 1960 that some cases were reported from States like West Bengal, Maharashtra, Mysore and Delhi. Polio is generally confined to the Urban Areas where protected water supply is available. Further, polio-vaccine has all along been an imported vaccine. It was decided by experts to concentrate on the areas where there were chances of polio outbreak in an epidemic form and considering all the facets of the problem it was decided to protect only the children who were under 4 years of age. No National Programme for immunisation against poliomyelitis has been contemplated since it was decided bv a panel of experts on 19-2-1970 that the vaccine should be made available for immunisation for those who demand it and also used for threatened epidemic."

Production of Polio Vaccine

1.17. Since there was no national programme for immunisation against polio, the Committee desired to know the basis on which the requirement of 1.20 crore trivalent doses of polio vaccine had been worked out. In a note, the Department of Health stated:

> "Fifteen per cent of total population falls in age-group of less than 5 year;. The estimate of 1.20 crore of trivalent doses is based on the assumption that no epidemic would involve more than 5 per cent of total population in India.

This would mean immunisation of 40 lakh susceptible population of children below 5 years. To ensure adequate dosages in the country for combating such an epidemic 1.20 crore trivalent doses would be needed."

1.18. According to the audit paragraph, preparation of batches of bulk vaccine had started at the Pasteur Institute, Coonoor, in December, 1966 and till May, 1973, apart from 4.61 lakh doses of trivalent vaccine (equivalent to 13.83 lakh doses of monovalent vaccine), the Institute produced only 63.91 lakh doses of monovalent vaccine. The Committee desired to know the number of doses of different types of monovalent vaccine produced by the Institute between June, 1973 and March, 1974. The Department of Health informed the Committee that during this period 5.20 lakh doses of type I monovalent vaccine and 0.50 lakh doses of type II inonovalent vaccine had been produced by the Institute.

1.19. In view of the limited production of polio vaccine at the Pasteur Institute, Coonoor, vaccine had to be imported to meet the country's requirements. The following table indicates the quantum and value of imports from 1966 to 1974 (upto August, 1974):

Year (January to December)	Country from which imported	Quantity imported in doses	c.i.f. value in Rupees.
1	2	3	4
1966	U.S.S.R.	6,15,000	1,01,501
	Yugoslavia	30,000	4,725
	Belgium	8,150	1,529
	TOTAL	6,53,150	1,07,595
1967	U.S.S.R.	7,85,000	1,31,508
	Yogoslavia	15,15,000	1,37,362
	TOTAL	23,00,000	2,68,870
1968	U.S.S.R.	5,00,000	70,000
	Yugoslavia	1,18,880	21,174
	TOTAL	6,18,880	91,174

1	2	3	4
1969	U.S.S.R.	6,69,350	91,609
	Yugoslavia	11,60,000	1,08,450
	TOTAL	18,29,350	2,00,059
1970	U.S.S.R.	7,94,000	1,05,602
	Yugoslavia	15,80,000	1,47,600
	TOTAL	23,74,000	2,53,202
1971	U.S.S.R.	33,20,000	4,41,560
	Yugoslavia	29,12,800	3,15,017
	TOTAL	62,32,800	7,56,577
1972	U.S.S.R.	77,52,000	9,59,568
	Yugoslavia	2,00,000	41,000
	TOTAL	79,52,000	10,00,568
1973	U.S.S.R.	24,57,500	3,28,248
1974 (Jan-Aug.)	U.S.S.R.	52,61,400	6,00,766

1.20. The Committee desired to know the reasons for the non-utilisation of the built-in capacity for the production of the vaccine at the Institute. The Director of the Pasteur Institute stated in evidence:

> "The preparation of this vaccine is a very sophisticated process and very few countries in the South Eastern region have undertaken this work. ... After studying the various aspects of the preparation of vaccine, we had to fix upon the jobs involved in the preparation of vaccine and also judge the competence of the person asked to be in charge of the various steps in the production, before we started

the preparation of vaccine in India for use in the country. The work was undertaken in spite of innumerable practical problems to be met with in regard to the project, with the hope that we will be able to solve the problems and achiwe production."

He added:

"The process of manufacturing is like this. We have to prepare various types of tissue cultures. The material which we use for preparing these things are unlike those used in foreign laboratories and sometimes when we prepare them, the culture fails. When the culture fails, the pace of the production is held up."

1.21. The Secretary, Ministry of Health & Family Planning stated in this connection:

"I have actually gone into this aspect along with the DG. He has been in-charge of the Institute and he has brought to my notice the Difficulty similar to the one which we are now encountering with regard to other vaccines. The period taken with regard to other vaccine that the country has produced is the same. Now, we have a successful production."

The Director General, Health Services added:

"I can talk with my little personal experience that this is a very sophisticated vaccine; it is a live vaccine; it can change its character. That requires a great deal of purity of chemicals, etc. Any slip anywhere will create difficulties in the overall production. The management techniques are as important as the question of chemicals and equipment. Steady supply of electric current is a must. There have been occasional failures of electricity in that region and if one such failure takes place, the work of a few months or sometimes a few years is put to a naught. We are thinking of maintaining coordination and cooperation between the scientists and the workers. As far as Coonoor is concerned, if you are not able to get the cooperation of the workers, the whole thing will come to a standstill. I have visited that place a number of times. There have been difficulties of the nature of the current as well as getting the cooperation of the workers There are so many factors responsible in the production of vaccine.

It does require a great deal of organisational skill.... There were some changes in the high echelon of the institute. One Director was retired and the other Director came in. We are doing everything in our power to see that the bottlenecks are removed....Right from 1968, I held four meetings for this very purpose. I have no locus standi except that I am deeply interested in solving these bottlenecks. All the bottlenecks with regard to storage, financial aid, technical competency and training were solved. We send people abroad for training purposes. Just now, the Director General had mentioned about the cell-line and their freedom from contamination and the high yield virus was to be maintained n the proper temperature. For this, I feel that something was not developed which we thought should have been developed and that resulted m lesser production. All this requires a very deep study."

1.22. Explaining the steps taken to improve the state of affairs at the Institute, the Secretary, Ministry of Health & Family Planning informed the Committee as follows:

"I would like to submit for your consideration that the moment we came to know about the state of affairs, we requested the ICMR to depute a senior officer. They had deputed Dr....to go into all these aspects and find out whether the testing facility by the Indian agency could be established. Dr..... has made a detailed study of the factors that have led to the present fall in production and in fact even in regard to this tight position they had encountered greater difficulties in the last year. This had also come to our notice and we have taken cognisance of this and we have taken remedial measures. A team of officers of ICMR, NICD, DGHS and the Drug Controller have also been on the spot and they are making the analysis of the whole situation. I frankly admit that this is being done after our attention has been drawn to the state of affairs."

1.23. The Committee desired to know the findings of the senior official of the Indian Council of Medical Research in regard to the study undertaken by him. In reply, the Department of Health furnished a copy of the findings of Dr.....relevant extracts of which are reproduced below:

"The following figures summarise the statistics about the production of vaccine:

Batch No,	Type	Sent for Neuro-Vir. Tests	Sent to	Quantity Litres	Report received in
I	I	May, 1968	Moscow	13·4	Jan. 1970
II	III	October, 1068	„	14·0	„
III	II	„	„	8·0	„
IV	I	December, 1969	„	17·2	November, 1970
V	II	„	„	10·2	„
VI	III	„	„	16·7	„
VII	I	January 1971	NICD, Delhi	1 5	May, 1972
VIII	III	„	„	18·5	July, 1972
IX	I	December, 1972	„	38·7	July, 1973
X	I	December, 1973	„	17.6	Not yet received.

The actual quantities of the final trivalent vaccine prepared were:

70-71	1,70,080	doses
71-72	98,850	„
72-73	1,72,500	„
73-74	19,350	„
	4,60,780	doses

(With the tested batches about 1·0 million final dose (trivalent vaccine) conar have been prepared)

The actual quantities issued were :

1971	1,10,000	doses to Delhi
Aug.73 to March 74	1,22,050	doses to Medical Store Depot, Madras
TOTAL :	2,32,050	doses

Balance in stock, about 1,96,000 doses all within the expiry date

All the final vaccine prepared is from Moscow tested bulk batches and none yet from NICD tested batches.

One has to concede that the development of Polio vaccine is not an easy procedure and the production of satisfactory batches takes time. However, as years pass by increase in the amount prepared has to occur. An increase in the tempo has not occurred. Even the bulk batches which have been tested have not been formulated and among the difficulties for doing so are:

1. Batches IV to VIII which have been stored have shown a loss of titre below the requisite level.

2. Preparation of further batches of Type II has not been possible because of some technical reasons (probably loss of titre in the seed virus or some snag in the method of processing).

I shall now give below my assessment of the several aspects of the work and facilities at the Unit.

Building: One could not desire a better facility. The building was specially constructed for the purpose.

Equipment: Excellent, adequate and maintained in very good condition (most of it supplied by WHO).

Electricity, water supply etc: No problems.

Supplies: Adequate. No major bottlenecks. Some difficulties in regard to foreign exchange matters and DGTD attitudes, but according to the Director there is no crisis at present. 12 Cercopethious monkeys have been recently imported, 2 have been used and the remaining 10 are in very good conditions.

Technical problem : Loss of titre in the bulk batches during storage; some difficulty with the seed virus type II; storage difficulties at the Madras Medical Store Depot.

Staff: Senior: Till now no problem but there will be problems soon.

Junior: The strength is adequate for the quantities required to be produed so far but would have to be augmented for larger prodution. But according to the Director their cooperation is unsatisfactory and he attributes this as the main cause for poor performance.

Reasons for low *production*

According to the Director lack of cooperation from the Junior staff is the main cause for the situation. In the past three has been quite a bit of trouble. Now that the Pasteur Institute staff has been separated and the ICMR staff have formed their own staff association (not a trade union affiliated to any outside body) with the office bears all from among the staff, the situation has altered. Further, with the setting of some old causes for trouble such as promotions, seniority etc. there does not appear to be any major staff problem though

the Institute staff are fighting for recognition and have appealed, it is said to the High Court. The units staff problems to my mind are not serious. This is a matter requiring development of better rapport between the officers and staff. It is a human problem which no one from outside can solve. The staff, individually and collectively, have assured me that they will do their utmost to improve matters.

There is a complaint that the staff do not work full time. The staff's point of view is that they do all the work allotted to them. When the matter was discussed with the Director he showed some recent work sheets according to which the work allotted on some days had not been completed. It appeared that the defect was due to carelessness on the part of some middle level supervisory staff who had not bothered to coordinate the activities. Further there seemed to be some lack of coordination between stores and the laboratories. The Director asked the officers as to why such difficulties were not brought to his notice but there as no satisfactory explanation. It seems to me that a better coordination can be brought about. Further it is rather too much to expect a Senior Research Assistant without experience in the control of staff duties and with no great appreciation of the urgency of the matter to set things right.

Programme of work : It seemed to me that a long range plan of work is necessary, with flow charts of various activities, fixation of targets of production, assignment of responsibilities and frequent and regular checks. In preparing the time tables due allowances have to be made for the contingencies which may arise. I have in mind the PERT* plan type of organisation. If there is such a plan then the defects and shortfalls are bound to come to notice in time and can be set right.

Assignment of duties: This to my mind is important. In any type of organisation each person should know that he will be held responsible for and to who is to report. Not that there is no assignment of duties now but thy are rather vague and there are too many categories of employees, Res. Assistants, Technical Assistants, Graduates Assistants and Lab. Assistants a it was not clear what type of work each as doing.

*PERT—Programme Evaluation and Review Technique.

Reorganisation of the Unit structure This may have to be considered soon. The present Director has a vast experience in the field of polio vaccines and may be expected to be available for at least two or three years more. His knowledge should be fully **utilised** and the unit put on firm footing before he retires. It may be essential immediately to look for a suitable full time officer-in-charge if the production has to be greatly stepped up.

If the unit should have a separate officer-in-charge the relationship of the unit to the Pasteur Institute has to be very intimate as it would have to use common facilities like water, electricity, animal houses etc.

Training of middle level staff is also very urgent. It seems very urgent to select and train one or two very well **qualified** microbiologists (virologists) to assume charge of some aspects of the work.

It would be useful if a small working group is appointed to study all the production problems and to suggest how the unit should be reorganised if found necessary. Apart from the Director, a virologist and an expert in production methods may be **associated** the group. A representative of the **Drug** Controller would also be desirable.

Technical problems: The low titres of the stores bulk vaccines call for close examination. Also the utilisation of the bulk vaccine promptly would prevent such problems. The status of seed viruses has to be ascertained, particularly of type **II.** The slow development of **neurvirulance** testing facilities at **MCD,** Delhi was at one time considered a bottleneck. It is no longer so. That unit has to kept supplied regularly with batches for testing Otherwise it may also be adversely **affected.** In fact, the whole programme of vaccine **production** testing, releases, etc. has to be a fully coordinate actively.

It is understood that a team of experts from **WHO** will be visiting **coonoor** in July 1974 to study the technical matters. Their report mag be awaited.

Separation of the ***vaccine*** production unit from rest of ***research*** activities.

The ICMR virus Diseases. Advisory Committee has recommended that the production of vaccine **should** be separated from the other research activities. This is a very desirable

step. I believe that ICMR has already taken some action in the matter. Such a step would enable vaccine production to be organised on a systematic basis. The Director agrees with this but he wishes that it should be under an independent officer, though having the closest touch with him for advice on technical matters. This is a matter which may be gone into carefully by the appropriate authorities.

In short, my personal assessment is that the Unit even with the present staff can effectively produce several million doses per year if a few essential steps are taken:

Preparation of firm plans for vaccine production, with time tables targets, assignment of responsibilities and checks and controls.

Recruitment of a few senior qualified and trained Staff. Training of the existing staff within the country or abroad as may be necessary.

Technical matters kept under scrutiny by the highest level.

Ensuring of better staff relations by better rapport.

There is likely to be some argument whether the unit should be called a 'Production Unit' or a 'Research unit' whatever the name is, a well thought out plan of production is necessary."

1.24. Relevant extracts from the report submitted by the team of officers of the ICMR, NICD, DGHS and the Drug Controller on the Pasteur Institute, Coonoor, furnished by the Department of Health, at the instance of the Committee are reproduced below:

"The Team was asked to make an on the spot assessment of various problems in connection with the production of oral polio vaccine in Coonoor. The various observations and recommendations are as follow:

Production of *Oral Poliovaccines.*

The bulk suspension coonoor 9|1 which was tested for its neurovirulence at NICD was reported to have lost its titre in one year at PIC. This bulk suspension was reported to be At for administration to children. PIC informed the team that the titre had fallen to such significantly low levels that it could not be incorporated in a trivalent vaccine.

There ere 1.96 lakh doses of trivalent vaccine in the stocks of PIC. The expiry dates for these batches are December 1974 and May 1975.

Instead of the planned use of 192 monkeys annually for *timal vaccine production, the actual numbers of monkeys used for production purposes during the past three years were 58, 92 and 87.

The Director, PIC explained the reduced output at 35 per cent level as being due to contamination and low virus titre.

The titre of the seed viruses for three serotypes was reported to be less than 107 TCID 50 per ml.

The team was informed that there was a stand-by generator but it was hardly put to any use. The possibility of installation of an automatic generator was discussed with Director, PIC. He felt that it would be a very cumbersome equipment to have since a full-time electronic engineer would be required to ensure that the generator was in working order.

Premises:

There was a complete breakdown in the measures that would have ensured sterility in the production chamber. This was apparent to the team on finding merely a strip of leucoplast being used to prevent flow of contaminated air from outside.

In one portion of the vaccine production building, material relating to rabies vaccine was being handled.

No attempt appears to have ever been made to check whether the germicidal lamps did possess, at a particular time on a particular day, any germicidal activity. In some of the rooms, the installed number of germicidal lamps on the ceiling-height did not appear to be powerful enough to produce a germicidal effect.

Equipment:

The electrical appliances appear to be in a, mess. The team found a box of Vim lying in an autoclave. Upon an enquiry from

a Lab. ,Attendant the team was told that the autoclave was being used as an almirah. There was no qualified electrician to look after the equipment and repair the minor electrical faults.

Records:

The records of vaccine production as well as the performance of deep-freezes, incubators and water baths etc. were incomplete and did not confirm to the International Standards. It was not possible to trace the registers which had been completed. There was no system of indexing of the completed registers.

Personnel:

There appears to be a gross dissatisfaction in the staff members employed in the polio-vaccine Production Unit owing to apathetic attitude of the Director, PIC and the Assistant Director. PIC. Some of the staff members said that even after 10—12 years of service they were temporary and had no avenues of promotion. They were not encouraged to undertake post-graduate studies or even publish scientific research papers.

The staff members contradicted the statement of the Director, PIC that there has been frequent power failure during 1973-74. They were positive in making the statement that their Institute had been exempted from power cut.

The staff members were dissatisfied owing to the preventable delay being caused in the implementation of the recommendations of the Third Pay Commission by the Director, PIC. It was reported by the staff that the necessary instructions had been received by Director, PIC from ICMR headquarters.

There appear to be a complete breakdown of even human and personal relationship between the Director, PIC, Assistant Director, PIC on one hand and the personnel employed in the Production Unit on the other hand. There was no doubt that the two parties mentioned above, talked to each other only in an accusing tone. The staff members were frustrated as they had virtually no work to do owing to lack of planning in advance. The entire production was in a confused stage.

RECOMMENDATIONS:

Production of oral Polio-Vaccines:

The entire stock of trivalent doses should be transferred to Madras on dry ice. These doses must be stored at—40°C to—70°C at Madras and distributed as early as possible.

The material relating to the bulk suspension Coonoor 9/1. anc Coonoor 10/1 may be discarded.

W.H.O. must be approached for fresh seed viruses from which working seed lots must be prepared. The team was informed about the imminent visit of Dr. W. C. Cockburn, W.H.O. Virology Chief to India and it is felt that this question could be discussed with him in detail.

It was felt that no useful purpose would be served by production/attempts of production of polio-vaccine by using the current seed materials at PIC which do not have satisfactory titres.

Systematic studies should be made to find out whether the bonnet monkeys are really resistant to the attenuated polio-viruses and free from extraneous agents. Necessary collaboration should be made with NICD, Delhi and other WHO reference' laboratories abroad.

The possibility of using continuous cell-lines like BSC—1 and Vero etc. as a substitutes to green monkeys might be explored. An early study carried out at PIC did not appear to be very convincing.

Premises.

Thorough investigations must be made to ascertain the factors responsible for contamination of production cultures. Prompt remedial measures must be taken to ensure that the newly obtained seed viruses are not contaminated with bacteria or fungi. Among other things the working of the autoclaves and the germicidal lamps has to be streamlined. It goes without saying that suitable air Alters including Lamier flow equipment in the produc-

tion chambers are indispensable for the efficient working of the production unit. The efficiency of the ultra-violet lamps must be checked every month. The atmosphere in the production chambers should be monitored for contamination by exposing agar plates and colony count after incubation. The sterility testing media for fungi could well be incubated at 22•‹C in addition to the current higher incubation temperatures.

Equipment:

Steps must be taken to ensure that in an event of power failure, the stand-by generator is invariably switched on. A fully automatic generator may well be indented now.

The total requirements of different items which have to be imported must be outlined. Immediate steps should be taken to ensure that there was. no interruption in the supply of materials vital for production.

Records:

The production protocols may be prepared in the same form as is the practice in other production centres abroad. No bulk suspension may be sent for neurovirulence testing till the production protocols have been prepared.

Personnel:

The team feels that the incompatibility between the staff members and the Director, PIC must be brought to an end as early as possible. It was felt that a wholetime young medical graduate should be the overall incharge of production. He should be expected to deal with all the problems relating to premises, personnel, supplies and the production of vaccines. To tune up the officer in-charge with the problems encountered in industrial production of polio-vaccine a fellowship might be arranged to enable the visit to Canada or U.S.A. There should be no link absolutely whatsoever between the PIC and the Officer-in-charge and staff members in the polio-vaccine Production Unit though the two could co-exist in harmony as separate entities in the same premises.

Epilogue

To take an on the spot decision regarding various problems relating to the production unit and to streamline some of the genuine difficulties of the staff members, a high-power committee comprising of D.G.H.S., I.C.M.R. and D.C.(I) may visit PIC and make on the spot decisions to avoid further delays and frustration in the polio-vaccine production.

The progress made by the Production Unit should be reviewed annually and remedial measures, planned and executed on a top-most priority. The annual reviewing could be carried out by the representatives of Directorate General of Health Services, Indian Council of Medical Research, Drugs Controller (India) and N.I.C.D."

1.25. In regard to the action taken on the recommendations of the team, the Department of Health informed the Committee as follows:

"A meeting to discuss the various recommendations of the team was convened on 13th September 1974 under the chairmanship of Director General of Health Services. It was decided that Director General of Health Services will convene another meeting on the 1st October 1974 to streamline the production and distribution of existing finished doses. This meeting was held in the room of the D.G. on the 1st October, as proposed."

1.26. Since regular supply of power was one of the important factors for maintaining the production of vaccine at an efficient level, the Committee pointed out that all the institutes should have independent power generating units. The Director of the Institute replied:

"We have a generator. If the anticipated power failure is for over half-an-hour, we switch on the generator; but it is not possible to do so in the night unless the watchman is able to find out the time for which the dislocation would be there or unless there is storm."

When the Committee observed that it should have been possible to instal an automatic generator, the witness stated that the question of installing an automatic generator was receiving attention. Explaining the reasons for not installing an automatic unit so far, he stated:

"We were told that we should have a group of electronic engineers; otherwise, automatic generators will not work. That is why it was not installed."

1.27. Since the production of the vaccine had also been affected on account of the non-availability of trained personnel, the Committee asked whether the staff had now been trained in the specialised procedures and how much time was lost in obtaining the trained staff. The Director General, Health Services replied:

"The qualifications presecribed for testing staff and those for production staff vary. With regard to testing, the NICD has now got a fully-trained staff and a very competent person in charge. We took about 2 years; but I would not say that production was delayed as a result. As the batches were being produced, the initial testing was done with the help of international laboratories in Russia and England, with whom we are collaborating. This has got no relevance to the production schedule of the vaccine."

The Committee desired to know why the necessity for training personnel had not been visualised earlier. The witness stated that the training of the specialist did not affect the production schedule.

1.28. The Committee desired to know the reasons for the variation in production of the three types of monovalent vaccine. The Director General, Health Services stated:

'There are 3 viral strains. Each of them behaves differently with regard to the pathogenocity of the disease and also the yield that it gives in the laboratories where it is being produced. Strain I nearly always yields a much lesser amount of viral bodies as compared to II and III. This is the experience all over the world. When we prepare all the three types, I is always lagging behind types II and III which are easier to produce."

When the Committee enquired whether all the three types were not required to produce the trivalent vaccine, the witness replied in the affirmative.

1.29. According to the Director of the Pasteur Institute, the production of the vaccine at the Institute had been less than the capacity as there was delay in getting imported monkeys, chemicals

end equipment. The Committee enquired whether for the preparation of the polio vaccine, only imported green monkeys could be used. The Director of the Institute stated in reply:

> "As has been explained earlier, for preparation and testing of polio vaccine, imported green monkeyg are necessary because of absence of certain virus in them."

A representative of the National Institute of Communicable Diseases stated in this connection:

> "If we were to exclude the possibility of contamination-by a monkey virus named S.V. 40, we have to depend on the tissues from African green monkeys. We can exclude the possibility of S.V.40—virus induced cancer in children following administration of polio vaccine, only by testing in tissues of African monkeys. There is no way out."

1.30. The Committee desired to know why it was difficult to impress upon the administrative authorities and the Director General, Technical Development that the requisite monkeys were not available in India and were to be imported for tests in connection with the preparation of live oral polio vaccine. The witness replied:

> "So far as the delay is concerned, I think, it may well be said that the authorities thought that it was better to verify that their import was necessary, before they sanctioned the import."

When the Committee pointed out that the import licence for 12 monkeys costing Rs. 11,000 was issued after 15 months, the witness stated:

> "Some correspondence was there. Whenever we had an opportunity, we saw the concerned officers. Then they were convinced that these had to be imported."

1.31. The Committee asked why a reference should have at all been made to the Director General, Technical Development for the import of monekys. The Secretary, Ministry of Health and Family Planning replied:

> "In respect of the first consignment of monkeys, they were presented by the WHO and there was no import duty to be paid; and we cleared it in three months' time. In respect of the second lot, we have been trying to get a chronological statement about the events.

The third lot was cleared in four to five months. From the statement I have, I find that the DGTD has given advance clearance; there was no delay on the part of the DGTD."

A chronological statement subsequently furnished in this regard by the Department of Health, at the instance of the Committee, is reproduced below:

No. of monkeys imported	Date of initiation of proposal for import	Date of issue of clearance by the DGTD	Actual date of import
10 monkeys supplied free of cost by the WHO	Ordered through the WHO on 24-2-1969	..	24-6-1969
11 monkeys	24-3-70	18-9-1970	24-10-1971
12 monkeys	10-5-73	18-9-1973	16-3-1974

1.32. The Committee enquired whether it was not possible to breed African green monkeys in India The Director General, Health Services replied:

"The monkeys are generally free from catching diseases than human beings. But they require a particular type of climate. The green monkeys cannot live in any other surrounding except in certain parts of Africa. Even if we are successful in breeding them in our country, the chances are that they will acquire this virus. But for our testing purposes, they should be free from all these things. Even if we get them here, the chances of their getting infected with other virus are more and we will not be able to make our experiment more successfully."

When the Committee asked whether the possibility of breeding green monkeys in India had been explored. The witness replied in the negative and the Secretary, Ministry of Health and Family Planning added that he would take note of the suggestion of the Committee and pursue it with the Veterinary Departments.

1.33. According to the Audit paragraph, import licence for 9 A. C. motors with inttrnal resisters (cost: Rs. 4,747). applied for in June, 970, was granted in April. 1972. The Committee desired to know why the concerned department took such a long time in arring at a decision on this issue. The Secretary, Ministry of Health and Family Planning stated:

"There was no delay on the part of the DGTD but last year this point regarding the requirements of equipment not only of these organisations but also hospitals came to my notice. We have requested the Finance Ministry to place at our disposal a certain amount of foreign exchange, so that we may be in a position to obtain these equipments."

The witness added:

"We are trying to remove all the bottlenecks. There was a discussion between ourselves, the Director General of Health Services, the Director General of the ICMR and the Ministry of Finance. DGTD is not to be blamed at all in this regard."

Explaining the reasons for the delay, he stated further:

"I can indicate briefly how the delay has taken place. In September 1970, the ICMR had approached the Ministry for the release of foreign exchange for Rs. 16,220. On 12th October, the Director General of Health Services was requested to offer comments. On 2nd November, the Directorate recommended that import in this case was not essential. On 10th November, DGTD's clearance given six months earlier was deemed to have expired. So, further clearance was also necessary. After that, the Ministry of Health also requested the Budget Section for the release of foreign exchange for ICMR for six months. On 7th February, the ICMR was informed that the stock was available and no import of the same was necessary. On 12th February, the Budget Section commented that Rs. 16,000 could be made available for the ICMR and the file was forwarded to another section. After that, there was a delay of 2 months. Then the ICMR had approached STC and asked for the release of foreign exchange for Rs. 11,519 to purchase the articles mentioned in the list. On this, the Ministry of Health asked ICMR for reconciliation of the discrepancy; because earlier, they had asked for Rs. 16,000 and after that, they had asked for Rs. 11,000. On 20th May, the ICMR reconciled the discrepancy and confirmed the amount as not Rs. 11,000 but 16,000. On 25th May, they referred it to the Budget Section for the release of foreign exchange and the Budget Section on 28th May asked for some clarification which was called for from ICMR on

10th June. Then there was a delay of two months. On 5th August, the ICMR clarified these points and again referred the case to the Budget Section on 9th August. On 28th August, the Ministry of Health referred it to the Ministry of Finance. On 14th September, the Ministry of Finance gave Rs. 3,000 under free foreign exchange facilities from Holland. On 20th September, they requested the Budget Section to release the balance amount and they did it on 21st September. On 23rd September, DGTD was requested to renew the earlier clearance. He gave the clearance on 8th October. From 10th December, the case was kept pending for want of allocation of foreign exchange by the Ministry of Finance regarding the Ministry of Health for the half year ending March 1973. There have been a number of cases like this. Now, they have got a standing arrangement that upto about Rs. 75,000, the Ministry can sanction the import on their own judgement, without having referred it to the different sections. This arrangement is in force since last year.... We have effected another change. I have called upon all the institutes to intimate in advance their requirement of foreign exchange regarding import. We are reviewing this thing every six months."

1.34. When the Committee asked whether the problem of delays in the issue of import licences and release of foreign exchange had not been examined earlier and resolved, the Secretary Ministry of Health and Family Planning replied:

"This concession was given to the State Governments and the private institutions. But, so far as Government departments are concerned, they have to go through the normal procedure of referring to different sections."

The Committee desired to know whether the same facilities which were available to the State Governments and private institutions were not available to Central Government departments. In a note furnished to the Committee, the Department of Health stated:

"The position as ascertained from the Chief Controller of Imports and Exports (Ministry of Commerce) is that although in the case of industrial undertakings in the private sector (including those in the public sector, which are not run departmentally by Central or a State Government), the requirement of foreign exchange is met

from the commercial ceiling, their import applications are subject to various checks and scrutiny by the licencing and sponsoring authorities. Licences are granted only if the applications are found to be complete in all respects and the various requirements of the policy have been met. On the other hand, in the case of industrial undertakings in the public sector, which are run departmentally by Central or a State Government, import licences are granted once the foreign exchange is released by the concerned administrative Ministry and indigenous clearance in respect of the stores to be imported has been received from the DGTD. In their case, import applications are not subect to various checks and scrutiny by the licencing authorities as in the case of private sector undertakings."

Testing of the Vaccine

1.35. A note furnished to the Committee by the Department of Health on the neurovirulence control of the vaccine and virologic control of the potency and purity of the finished, pooled lots of vaccine, is reproduced below:

"The neuro-virulence test is a test of comparison in which the virulence of the individual production batch is compared with the virulence of the corresponding reference material. The reference material is supplied by W.H.O after extensive field trials have been carried out to test its safety in human beings. In this test 60 to 70 monkeys are injected by different routes. After clinical observations for a period of 3 weeks their brains and spinal cord are examined for histological evidence of poliomyelitis.

The tests for potency and purity of the finished pooled lots of vaccine are meant to measure the quantity of the living virus in the vaccine. Additional tests are carried out to ensure that the vaccine contains no other viruses except the three strains of attenuated polio vaccine.

These tests are now being conducted by the National Institute of Communicable Diseases."

1.56. The Committee enquired into the reasons for the delay in testing the vaccine for neurovirulence and potency. The Director General, Health Services replied:

"This is a very sensitive and highly sophisticated vaccine requiring very rigorous standard of manufacturing and also of testing. The seed virus, as you must have heard, is a very tricky material to preserve and it has to be obtained by a certification from the WHO from only one particular source. Then the preservation of the seed virus also requires a great deal of effort to keep its titre and potency. The production of vaccine requires a number of tests. The vaccine is tested for several activities. All the time a check has to be kept for neurovirulence test. This is done in Indian monkeys. There are other viruses which can come from time to time. We have to see that monkeys for production are free from other extraneous viruses which are prevalent in the monkeys. One is which produces tumour. Animal requirements are also very sensitive. The potency of the vaccine is tested in a type of monkey which is normally available in this country. However, for tumour producing monkey virus, we need green monkeys. We have to import them from Africa. They are kept in England and then flown to India under very strict supervision. What I am trying to sag is that though it is possible to make this vaccine in this country, there are several stages and at every stage a great deal of caution and very careful attention is required."

The Director of the Pasteur Institute added in this connection:

"For a correct appreciation of the various problems and for interpreting the results, it would be important to know the kind of tests that have to be carried out. The monovalent vaccines have to be tested further by an independent agency, apart from a variety of other tests and since they had to be sent to foreign countries for this purpose, it naturally slowed down the pace. The first step of the preparation was to study the variations which can be used in the production process itself. This was achieved in collaboration with a medical institute of London. This collaboration was secured through the good offices of the regional WHO office in New Delhi."

1.37. According to the Audit paragraph, even after testing the monovalent vaccine in foreign countries, which took about 9 to 18 months, the approval of the Drug Controller could be obtained only after 5 to 8 months. Explaining the reasons for this delay,

a representative of the National Institute of Communicable Diseases stated in evidence:

> "Once the report of neurovirulence test is ready, it is sent to the Drug Controller of India and at the time of the test the producer, that is, the Pasteur Institute, Coonoor sends a protocol. Then the Drug Controller of India circulates the test report to the Committee of the ICMR, to the Representative of the Pasteur Institute, to the Representative of NICD and the DGHS. So, this procedure of approval of protocols took 5 to 8 months. Prior to 1970, facilities for this test were not available in the country and monovalent vaccines were being sent to foreign countries like USSR and we were depending upon the report of the Russians. Now, the facilities are available in the country and the tests are conducted in the Pasteur Institute, Coonoor Dr....., Ho Consultant, visited the NICD and also visited the Pasteur Institute, coonoor and there were some discussions held on this subject. We did not want to take any risk in this matter because it was live vaccine. That is why the delay was there. Now, it will not take more than two to three weeks."

1.38. Since the Audit Report pointed out delays in the testing of the vaccine in the testing division of the National Institute of Communicable Diseases also, the Committee desired to know the reasons therefor. The Director General, Health Services stated in evidence:

> "Production was not coming up to the required level. It came to our notice indirectly through a testing laboratory where they were waiting to receive a certain batch of vaccine. It did not receive the batch for six months and they wrote to the ICMR whose D.G. wrote to us. We are very much concerned about it."

1.39. The Committee desired to know the number of batches of vaccine tested by the division since its inception and details of the time taken in the completion of the tests after the receipt of the vaccine from the production unit. A statement furnished in this regard by the Department of Health is reproduced below:

Bulk	Vaccine No.	Date of despatch from production Unit	Received by NICD on	Test completed on	Report despatched from NIV on
Coonoor	7/1	May 71	19-5-71	4-4-72	25-5-72
Coonoor	8/3	May 71	19-5-71	15-7-72	18-7-72
Coonoor	9/1	Jan 73	10-1-73	17-7-73	18-7-73
Coonoor	10/1	Feb 74	11-2-74	21-6-74	24-6-74

1.40. While the vaccine was produced at Coonoor, the testing was done at New Delhi. The Committee enquired why the manufacturing unit had been established in one place and the testing centre at another place. The Director General, Health Services replied that the neuro-virulence test had to be done at the national level and added:

> "This centre was established in Delhi because it has to test not only the vaccine produced by the Indian laboratories but also the imported vaccine. At that time we were importing, and are still importing, a certain amount of vaccine from other countries like USSR and East European countries. This centre tests all these vaccines—whether produced locally or imported—and this has to be done at the national level and not to be left to the local laboratories because the results should be impartial and objective. In Delhi we have got the monkeys required for the purpose, the equipment and trained personnel and therefore it was considered suitable to have a central base rather than leave it to the local producing laboratories."

1.41. Even if the need for a national base was conceded, the Committee asked why Delhi had been chosen for twhe establishment of the testing division. The witness replied:

> "This is a very sophisticated vaccine requiring skilled people, a great deal of equipment and a special supply of monkeys kept under very controlled conditions. This could be developed at a much lesser cost at the National Institute of Communicable Diseases where a department of this nature already exists and, therefore, instead of duplicating it at another place, it was thought fit to centralise it here, away from the manufacturing centre—as we usually do not like to have the controlling agency located at the same place or near the place of the manufacturing centre."

1.42. The Committee drew the attention of the witness to the recommendation made by Dr. Albert B. Sabin, WHO Consultant, in his Assignment Report on the production of Live, Oral Polio virus vaccine in India (1963) that the neuro-virulence control of the vaccine should be done only once at an independent Government facility that would be located at or close to the institution where the neuro-pathologist selected for the job was then working.

Dr. Sabin had also recommended that the work should be entrusted to a neuro-pathologist then working at the Central Leprosy Institute, Chingleput, Tamil Nadu. The Committee desired to know why these recommendations of the eminent consultant had been overlooked. The Director General, Health Services stated:

> "When this proposal was made we thought of developing this competence at Delhi itself where all the material and pesticides were there and where we had a very eminent pathologist who was trained in this type of work in laboratories in England and Russia and who was also available at that time. At the time Dr. Sabin made the report these facilities at the National Institute of Communicable Diseases were not known to him or were not present."

On the question of proximity of the testing centre to the manufacturing centre, the witness stated:

> "The proximity is all right for us and it is not so important. We have got the ready means of transport and proper storage conditions. So, the distance is not as important a factor as the quality of the main equipment and other things."

1.43. Since the testing centre could, perhaps, have been established nearer the place of manufacture without much difficulty, the Committee enquired why this was not done. The witness replied:

> "So far as the laboratory equipments are concerned, it will mean duplication because in NICD these equipments were already available. We have a very nice monkey house where monkeys can be kept in a very good condition. The equipments are expensive which were imported from foreign countries and instead of duplicating them at another place, it was thought more economical to develop the competence."

1.44. The Committee desired to know the total recurring and non-recurring expenditure on the testing division upto March 1974. The Director General, Health Services stated:

> "The recurring expenditure is as follows:

1969-70	..	Rs. 2.24 lakhs.
1970-71	..	Rs. 2.65 lakhs.
1971-72	..	Rs. 3.02 lakhs.
1972-73	..	Rs. 3.25 lakhs.
1973-74	..	Rs. 3.25 lakhs.

The capital expenditure incurred predominantly for the construction of a special type of building is Rs. 4 lakhs."

1.45. In reply to another question of the Committee on the capacity of the testing division in the National Institute of Communicable Diseases, the representative of the Institute informed the Committee that the capacity of the testing division was about 16 million trivalent doses per year. When the Committee enquired how much of the capacity had been utilised, the witness replied that till 1974, the division had tested about 25 lakh monovalent doses, as against 19.2 crore monovalent doses that could have been tested. The Director General, Health Services stated in this connection:

"The testing laboratory has more or less unlimited capacity but it depends on the availability of monkeys. It depends on the producing capacity of the laboratories as to how much vaccine they should send for the testing. Now, as production capacity in the country is limited at the moment, we are hoping that Coonoor laboratory will be able to produce a larger amount of vaccine doses. The testing capacity is more than enough."

1.46. Since the production capacity of the Coonoor unit was only 12.50 lakh trivalent doses per year as against the capacity of 160 lakh trivalent doses in the testing division, the Committee desired to know whether there was any provision for the expansion of the production capacity. The Director General, Health Services stated:

"We are already going ahead with another unit at Haffkine Institute, Bombay. It is in an advance stage of development. In two years, they should be able to start manufacturing. At Coonoor itself, there is enough room and space. With additional augmentation of equipment etc., we would be able to augment the production capacity there also. The testing capacity is available for much larger quantity. The same capacity would be sufficient for 20 or 30 lakhs. We require only additional number of monkeys. The other material will remain the same."

Cost of production of **vaccine**

1.47. According to **the** Audit paragraph, while imported **vaccine costs** about 15 paise, the **cost of production** by **the** pasteur Institute

is about 50 paise per dose. When the Committee drew attention to this wide variation in costs, the Director General, Health Services replied:

> "The cost of production of vaccine is dependent on the quantity that is being produced. If we gradually increase the production with the same equipment, the cost of production progressively goes down. I was Director of another Institute and I know from practical experience that as we increase the quantity of production, the overheads being the same, the cost comes down."

1.48. The Committee desired to know whether the high cost of production at Coonoor was attributable to the inadequate utilisation of the capacity available or due to the high cost of raw materials or the absence of a suitable technology. The witness stated:

> "The most important factor is the expert knowledge, experience and the manufacturing practice. As I said earlier, contamination is a very important bug-bear of the production of vaccine. Improved techniques and the strict control that is to be followed, have to be ingrained in the people at all levels, in regard to handling the material. There was a heavy contamination rate in the earlier batches of production. It increased the cost of production. Secondly, when we produce vaccine in small quantities, the cost of production is always high. When we do it in large batches, there would only be a marginal increase in staff; but 10 or 15 times the quantity of vaccines can be produced. When the grouction reaches 30 or 40 times of what it was initially, the price comes down. All those vaccines that are now produced very economically have also gone through the initial process when the cost of production was very high. Once we master the technique and standardise things, the cost of production becomes very low."

When the Committee enquired whether the constraints had been overcome and sincere efforts were being made to reduce the cost, the witness replied:

> "They have agreed to set their house in order with regard to good manufacturing processes. Once this is done, the question of reducing the cost of production will arise."

1.49. The Committee asked what should be the optimum capacity of the unit to ensure a reduction in the cost of production. The Director General, Health Services replied:

> "This is a question which cannot be answered in an off-hand manner. The optimum capacity of a unit will depend on the equipment etc. Each individual laboratory will have to be assessed separately with regard to its production capacity."

He added:

> "We had done a little exercise in this respect. A Cost Accounts Unit was sent to Coonoor about three years back. They have worked out that this much would optimise the production and the cost of production would go down."

1.50. At the instance of the Committee, the Department of Health furnished a copy of the report of the Cost Accounting Team of the Central Research Institute, Kasauli and the cost analysis for the production of vaccine at Coonoor, which are reproduced in Appendix I. Replying to another question of the Committee on the action taken on the findings of the team, the Department stated that the review of the cost of production of the vaccine was under consideration of the Government.

1.51. Since the Haffkine Institute at Bom'bay was also to undertake the production of polio vaccine, the Committee enquired whether any economics of production and distribution at the Institute had been worked out and how the cost of production at this Institute would compare with the cost of production of the Coonoor vaccine. In a note, the Department of Health informed the Committee as follows:

> "Production of Oral Polio Vaccine at Haffkine Institute is likely to begin by end of 1975. In this connection a team of three WHO consultants has visited this Institute. They have made certain recommendations regarding the manufacturing facilities. On completion of these, production of Oral Polio Vaccine will begin at Haffkine Institute. This Ministry have no information whether the Government of Maharashtra or the Haffkine Institute have worked out the economics of production and distribution of vaccine. Since the Haffkine Insti-

tute is not manufacturing the vaccine at present, the question of comparing the cost with cost of vaccine being manufactured at Coonoor does not arise.

Haffkine Institute has been importing concentrated bulk oral polio vaccine since 1962. This bulk vaccine is processed, tested and then distributed all over the country. Approximately 3 million doses of trivalent vaccine is distributed every year. This imported vaccine is supplied at the rate of Rs. 0.33 per dose. As against this, the price charged for the vaccine produced at the Pasteur Institute, Coonoor, is Rs. 0.38 per dose for bulk consumers and Rs. 0.50 per dose for individuals."

Distribution and sales

1.52. According to the Audit paragraph, even though it had been decided in June 1971 that trivalent vaccines would be distributed through the Medical Stores Depot, Madras, distribution of the vaccine through the depot, however, started only in August 1973. The Committee desired to know the details of the vaccine distributed or sold by the Medical Stores Depot, Madras. In a note, the Department of Health stated as follows:

"The Madras Medical Store Depot distributes/supplies oral polio vaccines to different hospitals, Directorates of State Health Services, Municipal Corporations, District Medical|Health Officers and Medical College Hospitals. Additionally vaccine was also distributed through Medical Stores Depots, in Bombay and Hyderabad."

1.53. The Committee desired to know the quantity distributed/sold from December 1966 onwards. In another note, the Department stated:

"A total of 1.10 lakh doses of polio vaccines were supplied in 1971 to NICD for use in Delhi directly by the pasteur Institute, Coonoor. The quantity distributed/sold from August 1973 onwards through Medical Store Depot, Madras is 1,78,820 doses."

1.54. In reply to another question whether all the trivalent doses produced so far had been sold, the Department of Health informed the Committee that all except 1.71 lakh doses had been sold.

1.55. On account of the delay in marketing the vaccine, the Audit paragraph points out that the date of expiry of 0.60 lakh doses was over in July-August, 1972 and those doses had to be re-titrated and the period of their usability extended upto April 1975 by the Drug Controller. The Committee desired to know the efficacy of using retitrated vaccine. The Director General, Health Services stated:

> "It was done on a very scientific basis. When we produce a large quantity of vaccine, we estimate a particular expiry date. It is a very expensive vaccine. At the end of the period, we test it again to see whether the vaccine can last any longer. We test the titre. If we feel that because of good storage conditions, the titre continues to remain what it was at the time of manufacture, we then extend the period of expiry by another 2 or 3 years or for any other suitable period, depending upon many other factors. Therefore, if the titre has been tested at the time of the expiry date, in the control laboratory and if that is found satisfactory and up to the desired level, we can easily extend the expiry date for a suitable time. If some batches have been supplied in the field, I would not like to use them after the expiry date because there is a difference between the ideal conditions under which this can be kept in the laboratory and in the field."

1.56. The Committee asked how long the vaccine could retain its potency, if it was stored at minus 20•‹C.The representative of the National Institute of Communicable Diseases replied:

> "If the vaccine is kept at minus 20•‹Cand there no power failure, there should not be any significant loss in the potency or the deterioration of potency for 5 to 10 years."

He added that if it was kept at room temperature, the loss in potency might be found within a few hours.

1.57. Explaining the conditions and factors under which the period of expiry of the vaccine could be extended, the Department of Health, in a note, stated as follows:

> "In case the vaccine have been stored throughout at minus 20°C and have not been sent to field, there is a *prima facie* case for retitration and extending the period of *expiry* on the basis of the report on retitration!'

1.58. The Committee desired to know whether the 0.60 lakh doses of vaccine, which had been retitrated, had already been supplied to the field. In a note furnished to the Committee, the Department af Health stated:

> "0.60. lakh doses of trivalent oral polio vaccine stored at or below—20°C were retitrated at the Pasteur Institute, Coonoor, National Institute of Communicable Diseases, Delhi and at the Haffkine Institute, Bombay. It was confirmed by all the three laboratories that vaccine has retained its potency. This vacine is stored at the Pasteur Institute, Coonoor and at the Haffkine Institute, Bombay awaiting distribution and can be used for the immunisation of children before 17-4-1975, *i.e.*, within 2 years of the date of retitration. The vaccine has been approved for use by accepted standard criteria."

1.59. The Committee referred to certain reports in the foreign press on the failure of polio vaccine supplied to Calcutta in 1972 and desired to know if these reports were correct and, if so, whether the causes for the failure had been investigated. The Director General, Health Services stated:

> "I would say that we have issued strict instructions that date-expired vaccine should not be use?. This is a very sensitive vaccine and I, as a scientist and administrator, would never permit it to be used in the field."

The Director of the Pasteur Institute stated in this connection:

> "I think the vaccine manufactured in Coonoor was not sent to Calcutta. That has to be verified."

The Director General, Health Services added:

> "The vaccine is being supplied from Coonoor, but my information is that that was supplied to Calcutta from there. The other is concentrated vaccine imported from Russia, stored in Bombay Haffkine Institute, diluted to the requisite potency and sealed in the ampules and then supplied to the rest of the country. It can be the vaccine sent by Haffkine Institute. I will verify and tell you."

1.60. Subsequently, in a note furnished to the Committee in this regard, the Department of Health informed . the Committee as follows:

"The information as supplied by the Director of Health Services, West Bengal states that there had not been such an incident in 1972. The vaccine was supplied by the Haffkine Institute, Bombay. No request for investigation has ever been made to the Central Government|Directorate General of Health Services."

A copy of the letter dated 18th August 1972 received in this connection from the Directorate of Health Services, West Bengal by the Director General, Health Services, Government of India was also furnished to the Committee by the Department of Health, which is reproduced below:

"With reference to your letter dated the 28th July, I am to inform you the following facts in reply to the points raised in your said letter.

Vaccine received from Haffkine Institute was kept continuously under deep freeze till use. Once drawn, the same vaccine was used within 'the next fortnight. During this time it was kept in a refrigerator.

The temperature of deep freeze was minus 20•‹C.

The maximum period beyond the date of expiry marked by the Haffkine Institute by which the vaccines were used never exceeded 2 months.

A short summary of the present incident as reported in the Manchester Guardian and also Times, London, is given below:—

The vaccines imported from Haffkine Institute is usually in the Department of Virology, Institute of Post-graduate Medical Education and Research, Calcutta. It is the practice to keep the vaccine in a deep freeze as soon as it is obtained. As and when necessary the vials are taken for use and stored at plus 4•‹C in a refrigerator. Once drawn the 'vaccine was never used for a period exceeding a fortnight.

Because the vaccines were used beyond the expiry date, a certain doctor informed the Health Minister about the use of vaccines beyond the expiry date. This was enquired into by the Director, Drug Control, who observed that the vaccines were properly stored in a deep freeze.

This information was published in a local newspaper alleging that useless vaccine was being used in the Government hospitals. This news was completely distorted and published in the newspapers of England by Reuter where it was alleged that 'thousands of children dying of poliomyeltis in Calcutta'. So far as our information goes there is no increase in the incidence of poliomyelitis in Calcutta in recent years. Furthermore, there was no report of a single case of poliomyelitis occurring in any of the children taking the vaccine from the said source at IPGM&R from the time oral vaccine was introduced in our state, *viz.*, 1964. It will be found therefore that the entire news is not only fictitious but is also malicious and motivated."

GENERAL

1.61. The Committee desired to know whether any mechanism was available with the Government to educate the people in the rural areas on poliomyelitis. The Director General, Health Services stated:

"On health education in rural areas as such it is rather deficient and poor and to that extent, apart fhom radio news and apart from some of the health bulletins which are published by our Bureau of Public Health, both in Hindi and English, there is no organised effort on anti-poliomyelitis in the rural areas."

He added:

"In the hospitals when the people come and wait for getting treatment, Health Inspectors come and personally tell them about this. Moreover, the pamphlets are put up before them and they are also distributed to the patients. Then of course we publish this in the newspapers and also inform the people through radio network."

1.62. The Committee asked what measures had been taken or were contemplated to, educate the masses about the utility of administering polio vaccine. The Director General, Health Services staed in evidence:

"In those areas where the disease is likely to spread we go and educate them with the help of slides and other audio visual things. Otherwise, there are publications by the Cntral Bureau of Health Education which bring out pamphlets on polio both in Hindi and English and they are available to the public in the hospitals."

1.63. The Committee were informed by Audit that in a meeting held on 26th June 1971, under the chairmanship of the Director General Health Services, it had been reported that the following aspects of polio were being studied under the auspices of the Indian Council of Medical Research:

(a) polio mortality survey in selected areas;

(b) surveillance for polio in selected localities; and

(c) laboratory studies of polio cases, etc. The Committee desired to know the results of these studies and whether any other surveys or research on polio had been undertaken by the ICMR or other agencies. The Committee also enquired whether there was any system for exchange of information on studies conducted by the ICMR with the Pasteur Institute. In a note, the Department of Health stated:

"A collaborative study on the prevalence of enteroviruses in India with special reference to poliomyelitis has been in progress under the Council since 1972 at four centres, viz., (1) Medical College, Nagpur, (2) Bangalore Medical College, Bangalore, (3) B. J. Medical College, Ahmedabad and (4) K. G. Medical College, Lucknow. The objectives of the study are as follows:

1. A polio morbidity survey in representative sections of the country.
2. Surveillance for polio in selected localities.
3. Studies on non-polio enteroviruses.
4. Development and strengthening of laboratory facilities.

It was proposed to undertake the study in two phases. In the first phase of the study, poliomyelitis survey in urban and rural areas has been conducted. The preliminary

analysis of the data suggests that incidence of poliomyelitis is similar in both urban and rural areas with the only exception of data from Bangalore. The second phase of the study on the prevalence of enteroviruses and efficacy of polio vaccine is in progress.

It is expected that the result of this study after successful completion would help in assessing the problem more realistically than at present and help the health administrator to come to some decisions regarding the polio vaccination policy.

The progress report of the ICMR Research Unit at the Pasteur Institute, Coonoor and the progress reports of the colloborative studies on poliomyelitis are reviewed and discussed annually by the Expert Committee on Virus and Arthrcpod Borne Diseases or' the Council of which Dr....., Director, Pasteur Institute, Coonoor is alsq a member.

The following research projects on polio have also been undertaken by the Council:

1. Enterovirus Unit under Dr..... at the Haffkine Institute, Bombay.

2. To investigate the role of viruses in Central nervous system diseases in children: under Dr.....Christian Medical College and Hospital, Vellorc."

Recommendations

1.64. The Committee are extremely dissatisfied with the performance and achievements of the polio vaccine production unit at. the Pasteur Institute, Coonoor on which, as pointed out by Audit, Rs. 21.15 lakhs, excluding foreign aid of Rs. 7.48 lakhs, had been spent upto March 1972. They are concerned to note that as against. its annual capacity of 12.50 lakh trivalent doses of vaccine, the unit has been able to produce only 4.61 lakh trivalent doses from December 1966 to May 1,973, in a span of about 64 years. The average annual production, thus, works out to only about 6 per cent of the capacity of the unit. Even conceding that the development of the vaccine is a sophisticated process and the production of contamination-free batches takes time, the present state of affairs at the Institute is far

from satisfactory. The Committee apprehend that unless vigorous and concerted efforts are made to improve production and management techniques at the unit, the position may well become irretrievable.

1.65. In this context, the Committee are of the view that the assessments made by a senior official of the Indian Council of Medical Research and by a team of officers of the Council, the National Institute of Communicable Diseases, Directorate General of Health Services and the Drug Controller, who had been deputed to conduct, a detailed study of the shortfalls in production. are of considerable significance and merit serious and immediate attention. The picture that emerges from these two studies is far from complimentary both to the production unit and the Pasteur Institute. The following facts, in particular, bring out the sad state of affairs prevailing in the Institute:

(a) Lack of cooperation and rapport and a complete breakdown of human and personal relationships between the personnel of the production unit and the Director of the Institute;

(b) carelessness on the part of middle level supervisory staff in coordinating the activities of the unit;

(c) absence of a long range plan of work. non-fixation of targets of production, non-assignment of responsibilities and the absence of frequent and regular checks:

(d) non-availability of trained middle level staff;

(e) a complete breakdown of the measures that would ensure sterility in the production chamber; and

(f) inadequate maintenance of equipment and records.

1.66. The Committee attach considerable importance to the recommendation of the study team that the vaccine production unit should be placed under the overall charge of a wholetime officer who would be expected to deal with all the problems relating to premises, personnel, supplies and the production of vaccine. The Committee accordingly recommend that decision on this recommendation should be taken without further delay so as to place the production unit on a firmer footing.

1.67. The Committee learn that the present Director of the Pasteur Institute, who has vast experience in the field of polio vaccines will be available for only another two or three years. The problem of his

replacement, when no longer available, calls for careful thought. It is, therefore, imperative that a sufficient number of persons are trained in the techniques and intricacies of production of polio vaccine so that production does not suffer in the years to come on account of the non-availability of suitable trained personnel. The Committee desire that urgent steps should be taken to impart necessary training to a sufficient number of middle-level staff who could effectively discharge the responsibility of overseeing the technical aspects of production.

1.68. In the opinion of the Committee, some of the technical problems brought to their notice during their examination are also not entirely insurmountable and are attributable more to negligence and carelessness. For instance, the Committee are surprised to learn that no attempt appears to have ever been made to check whether the germicidal lamps did possess, at a particular time on a particular day, any germicidal activity. Similarly, the electrical appliances are stated to be 'in a mess'. It is, therefore, obvious that effective supervision and prompt remedial measures have been inadequate, if not altogether non-existent. Since the technical aspects of production imperatively call for constant scrutiny, the Committee cannot countenance such lapses in the production of a sophisticated vaccine. They desire that responsibility should be fixed for the non-observance of even the basic, elementary requirements of successful production.

1.69. The Committee are of the view that the malady of the vaccine production unit at Coonoor is far more deep-seated than what meets the eye and the two studies emphasise the need for far-reaching changes and remedial measures. The Committee learn with consternation of the lack of cooperation and the complete breakdown of human and personal relationships at the Institute and this should also cause great concern to Government. The Committee desire that the functioning of the unit should be comprehensively and expeditiously reviewed in the light of the analysis already made by the two study teams and urgent steps taken to remove the existing bottlenecks and obstacles and to streamline the production of the vaccine. The Committee note that a meeting had been held on 1st October 1974 to consider the recommendations of the Study Team and would like to be informed of the measures, if any, already taken in pursuance of these recommendations.

1.70. It is also seen from the ICMR official's report that a team of experts from the World Health Organisation was scheduled to visit the Pasteur Institute at Coonoor in July 1974 to study the technical

aspects of vaccine production. The Committee would like to be informed of the findings of this team and the action taken by Government on its recommendations.

1.71. The shortfall in production of the vaccine at the Pasteur Institute has also been attributed by the Director of the Institute to delays in the import of African green monkeys, chemicals and equipment. The Committee have been informed that while there was a delay of about six months in the issue of clearance by the Director General, Technical Development in respect of the import of 11 monkeys in 1970, necessary clearance had been issued by the Director General, Technical Development after 4 months in respect of a further import of 12 monkeys in 1973. The Committee are concerned over such delays in arranging imports of a vital prerequisite for the production of the vaccine. The Committee are of the view that it should be possible to streamline the existing procedures for the issue of clearance by the Director General, Technical Development at least in respect of such imports by Central Government departments and organisations for which the justification is beyond doubt. The Committee desire that this should be examined and a suitable, simplified procedure evolved.

1.72. The Committee note that certain changes have been effected in the existing arrangements for sanctioning imports and the Ministry of Health has been empowered to sanction imports. up to an amount of Rs. 75,000, on their own judgment without referring the case to different agencies. The Committee trust. that with this arrangement, the bottlenecks in imports would be considerably eliminated. The Committee would like to be informed of the time now taken, after the introduction of the revised procedure, for arranging imports of monkeys and other equipment etc. required by the Vaccine Production Unit.

1.73. The Committee desire that the possibility of breeding African green monkeys in India in a virusfree form. so as to reduce the dependence on imports, should be explored on a priority basis. The Committee take note of the assurance given by the Secretary, Ministry of Health and Family Planning during evidence that this suggestion would be pursued with the Veterinary Department and would like to be apprised of the progress made in this regard.

1.74. The Committee have been informed that the production of vaccine is also liable to be affected by power failures and are surprised to learn that an automatic generator has not been installed so far.

Since regular supply of power is one of the important factors for maintaining production of vaccine at an efficient level and its proper storage, the Committee desire that this deficiency should be made good on a priority basis.

1.75. The Committee are concerned to observe that the approval of the Drug Controller for the preparation of trivalent vaccine from the monovalent doses of vaccine produced at the Institute and tested in foreign countries had been communicated only 5 to 8 months after the receipt of the test results. In the opinion of the Committee, this delay was by no means unavoidable. It is surprising that the circulation of the protocols by the Drug Controller to various agencies entrusted with the certification of the vaccine should have taken 5 to 8 months and the reasons advanced by the Ministry for this delay are not at all convincing. The Committee, however, note that the procedure has now been streamlined and that the certification by the Drug Controller would not take more than 2 to 3 weeks. The Committee trust that the revised schedule for the testing of the monovalent doses of the vaccine would be rigidly adhered to and prompt action taken to remedy the situation whenever delays of avoidable magnitude come to notice.

1.76. While the Committee can understand the reasons for the delays involved in the testing of the monovalent, doses of vaccine in foreign countries, they are unable to appreciate the delays that have occurred at the testing division, established in the later part of 1970, in the National Institute of Communicable Diseases, New Delhi. The Committee find that the tests in respect of two batches of vaccine received in May, 1971 had been completed only after 11 months in one case and 14 months in another case. Though the time taken for the test has been reduced in respect of two subsequent batches received by the division in January 1,978 and February 1974, the Committee are still unhappy with the performance of the testing division. The Committee would. therefore, like Government to investigate the reasons for the delay in testing the vaccine at the National Institute of Communicable Diseases and take suitable remedial measures to avoid recurrence of such delays. The Committee would like to be apprised of the action taken in this regard.

1.77. It is also a matter of concern to the Committee that the capacity of the testing division (on which, till March 1972, Rs. 11.45 lakhs had been spent, excluding cost of buildings) has been grossly underutilised so far. The Committee note that only 25 lakh monovalent doses have been tested by the division till 1974 as against 19.2 crore monovalent does that could have been tested. The underutilisation

of testing capacity has been mainly attributed to the existing limited capacity for production of the vaccine in the country and the delays in the receipt of batches for testing. However, even after streamlining the production at the Pasteur Institute so as to achieve the optimum capacity of 12.50 lakh trivalent doses, the percentage utilisation of the built-in capacity of the testing division would still be only about 15 per cent. The Committee are also doubtful whether, even after the establishment of another production unit at the Haffkint Institute, Bombay, it would be possible to utilise the full capacity of 160 lakh trivalent doses of the testing division. The Committee would like to be informed of the basis on which the existing capacity of the division has been worked out. Government should also examine immediately the feasibility of effecting economy in the expenditure on staff etc. of the testing division.

1.78. It is also significant that while the cost of imported polio vaccine works out to only about 15 paise, the cost of production at the Institute is about 50 paise per dose. Considering the wide disparity in the cost of imported and indigenous vaccines, the Committee desire that urgent steps should be taken to reduce the cost of production by improved techniques. In this connection the Committee have been informed that an exercise in this regard had been carried out by a Cost Accounts Unit in 1968 and that the review of the cost of production at the Institute is under consideration of the Government. It is deplorable that no action has yet been initiated on the report of the Cast Accounts Unit, even after a lapse of more than six years The Committee take an extremely serious view of this delay and desire that responsibility should he fixed for the lapse and appropriate action taken under advice to them.

1.79. Now that the Haffkine Institute, Bombay is also expected to commence production of oral polio vaccine by the end of 1975, the Committee would like the economics of production and distribution of the vaccine at this Institute to be worked out in detail, in case this has not already been done, and intimated. The Committee also trust that the production at this Institute would b* geared up and streamlined even in the initial stages in the light of the experience gained at the Pasteur Institute. The Committee expect that in this task there would be no lack of coordination, which appears to be feared, between the Institute, the Government of Maharashtra and also, of course, the Central Government. The Committee would be watching the performance of the Haffkine Institute with interest.

1.80. The Committee note that 1.71 lakh doses of polio vaccine supplied to the Medical Store Depot, Madras had remained unsold towards the closing months of 1974 and would like to be informed of the present position of sales at the Depot.

1.81. The Committee find that on account of the delay in marketing the vaccine, the date of expiry of 0.60 lakh doses was over in July-August 1972 and consequently, these doses had to be retitrated and the period of their usability extended upto April 1975. The Committee would like to know the additional expenditure incurred in retitrating these doses and whether the entire quantity of 0.60 lakh doses has been utilised, now that even the extended period is over. That such a measure was necessary would indicate the need for improving the facilities available for marketing the vaccine and apparently sufficient attention has not been paid to this important aspect. The Committee desire that the adequacy of the existing marketing arrangements should he reviewed and necessary remedial measures taken.

1.82. The Committee are concerned to find that there has been no organised effort to rouse public awareness on anti-poliomyelitis in the rural areas. No national programme for immunisation against poliomyelitis has yet been contemplated though epidemics of polio have occurred in the country and relative to need, the efforts so far made are very limited and modest. The Committee consider it important that adequate measures are taken to educate the masses, particularly in the rural areas, on polio and the efficacy of oral polio vaccine which Government should make every possible effort to provide in required quantity and quality. The Committee are of the view that the existing arrangements in this regard are far from adequate, and a more earnest and organised effort is called for. The Committee suggest that Government should, inter alia, utilise the powerful medium of films and radio so as to make a sustained impact on the rural population.

1.83. The Committee also find that it has been estimated that out of the population of 54.80 crores, according to the 1971 census, 8.20 crore children are in the susceptible group, for whom 24.60 crore doses of trivalent polio vaccine are needed annually. Besides, for the estimated 1.30 crore new-borns, about 3.90 crore doses of trivalent vaccine are also required each year. Yet, the Committee are surprised to find that the country's annual requirement of polio vaccine has been presently estimated as only 1.28 crore trivalent doses. Apparently, the requirements have been placed at 1.20 crore doses as against the actual estimates of 28.50 crore doses

on the basis of the expert view that the vaccine should be made available for immunisation for those who demand it and also used for threatened epidemic. The number of doses actually available in the country (both imported and indigenously produced) has been much less than even this estimate. The authorities concerned seem to derive comfort from the fact that as the epidemic declines, the public lose their enthusiasm for immunising the children and fail to give the three doses necessary to each child to ensure proper immunisation. In the opinion of the Committee' this seems to suggest a certain complacence in regard to public indifference, not unnatural in Indian conditions, towards serious health hazards. That such a situation has been allowed to persist only underlines the urgent need to adequately educate the public on the dangers of polio and the measures to combat this acutely infectious disease.

1.84. The Committee understand that while [tap water is free from the virus of poliomyelitis, it is most dangerous to use water available from hand-pumps. While explaining the reasons for not contemplating a national programme for immunisation against polio, the Director General, Health Services had also stated that only by supplying protected water to the entire country, this disease can, to some extent be eradicated and that if this could be ensured, then there would be a national programme. The Committee would 10e to know the concrete steps taken by Government in this direction.

NEW DELHI;
July 24, 1975.
Sravana 2, 1897 (S)

H. N. MUKHERJEE,
Chairman,
Public *Accounts* Committee.

APPENDIX I

(*Vide* Para 1.50)

Report of the Cost Accounting Team of Central Research Institute, Kasauli regarding the cost of *production* of Oral Poliovaccine Manufactured at the Pasteur Institute Southern India, *Coonoor*.

In pursuance of the instructions issued by the Director General of Health Services, New Delhi *wide* his letter No. 1426/66-PH (CD&L) dated the 2nd August, 1968, the Cost Accounting team of the Central Research Institute, Kasauli comprising of an Accounts Officer (Shri V. S. Bhalla), one Cost Accountant (Shri K. K. Guptn) and a Cost Assistant (Shri Hari Chand) visited Pasteur Institute, Coonoor from 20.12.1968 to 25.12.1968 to work out the cost of Oral Poliovaccine.

2. All the relevant records and accounts data relating to the Production of Oral Poliovaccine have been examined. As per information made available to the team, the Polio Unit started its preliminary work in January, 1964 after completion of the construction of laboratories, cold rooms etc., and installation of essential machinery and equipment. The preparation of seed virus was completed in March, 1966, and it was sent for preliminary test to Medical Research Council, London. The seed viruses were sent to London for final test in October, 1966, and the results on all the three seed viruses were intimated to be satisfactory by June, 1967. The preparation of batches of bulk vaccine was started in December, 1966, and by September 1968 the Polio Unit had produced 3 million doses of monovalent vaccine which would give about one million doses of trivalent vaccine containing attenuated strains type 1, 2 and 3. The vaccine is awaiting release pending receipt of results of neurovirulence testing of some batches from the Institute of Poliomyelitis and Viral Encephalitis, U.S.S.R. Academy of Medical Sciences, Moscow. The total expenditure of non-capital nature incurred upto the end of September, 1968 (during the period from 1962 to September 1968) on the production of 3 million doses of monovalent oral poliovaccine or 1 million doses of trivalent vaccine, aggregated Rs. 15,51,494.00. On this basis, the cost per dose of trivalent oral poliovaccine works out to Rs. 1.55 per dose, vide I Cost sheet attached. This cost is, how-

ever, unrealistic as the work done in the earlier years in connection with the production of the Poliovaccine was necessarily of a preparatory nature (involving as it did the training of staff, research and development of production techniques and finalisation of arrangements of testing of the seed viruses as also the batches of the vaccine). Also, on account of various reasons the production was not maximal. The expenditure incurred during the entire period from the inception of the Polio Unit at the Pasteur Institute of Southern India, Coonoor, should not, therefore, legitimately constitute the basis for working out the production costs. It would be more equitable and reasonable to take into acount the estimated normal production and anticipated expenditure of one year only for the purpose of arriving at a reasonably correct picture of the cost of production.

It has been estimated by the Institute authorities that under normal conditions and with the existing staff, machinery equipment etc., they will be able to produce nearly 1.25 million doses of trivalent oral poliovaccine per year. Accepting this as a base, and taking into accounts the estimated expenditure of one year (base on the actual figures of expenditure for the year 1967-68 plus the probable extra expenditure on chemicals involved in the production of 1.25 million doses of the vaccine), the cost inclusive of bottling and labelling charges comes to 50 paise per dose *vide II* Cost Sheet attached. This cost is exclusive of packing and forwarding charges but includes a contribution of 2 Paise per dose to be paid to Pasteur Institute, Coonoor and 10 per cent departmental charges of the Medical Stores Depot, Madras, as per decision embodied in Para 6 of the minutes of the meeting of the Sub-Committee on the production, distribution storage and supply of oral Poliovaccine held in New Delhi on the 23rd November, 1967.

The facilities for doing the test for the absence of SV 40 Virus in the batches of viruses fluid are not yet available in India. Arrangements are being made to import the species of monkeys required for the test from outside India through the financial help of the W.H.O. Regional Office of South East Asia, New Delhi. A large number of batches of vaccine are awaiting completion of this test. The arrangements to carry out neurovirulence testing of the Poliovaccine are being made by the Government of India at the National Institute of Communicable Diseases, Delhi. The set up at the National Institute of Communicable Diseases is awaiting the arrival of a consultant to be provided through the good offices of the W.H.O. Regional Office for South East Asia, New Delhi, to start functioning. Until finalisation of these arrangements, the Polio Unit at the Pasteur Institute. Coonoor has inevitably, to restrict production to the barest minimum.

With the availability of necessary testing facilities in India, and employment of the full complement of staff, the production is expected to go up substantially resulting in the lowering of cost of production progressively. The cast of production now worked out is more or less tentative based as it is on the estimated figures of production and expenditure of one year. The production costs will, therefore, need to be reviewed when the normal production level is reached.

Sd/- V. S. Bhalla.,
Officer-in-Charge, Costing Team,
Central Research Institute,
Kasauli.

Camp: Pasteur Institute
Coonoor-3
Dated: 25th December, 1968.

1: COST IN RESPECT OF THE PRODUCTION OF 1 MILLION DOSES OF TRIVALENT ORAL POLIO VACCINE AT THE PASTEUR. INSTITUTE OF SOUTHERN INDIA COONOOR FROM THE INCEPTION OF THE POLIO VACCINE UNIT TILL SEPTEMBER, 1968

Particulars		1960-61	1961-62	1962-63	1963-64	1964-65
		Rs.	Rs.	Rs.	Rs.	Rs.
Chemicals consumed		..	..	..	..	2,36
Establishment Charges (Pay & Allowances & C.P. Fund contributions)			..	..	14,286	96,415
Animals and their upkeep		..	..	..	4,463	5,375
PRIME COST :	(a)	..	..	..	18,749	1,03,826
1. DEPRECIATION CHARGES						
(i) Buildings		..	..	..	12,589	49,728
(ii) Plant & Machinery		..	..	1,700	21,067	62,307
(iii) Scientific Apparatus & Laboratory equipments		..	..	1,081	3,623	10,920
(iv) Furniture & Fittings and Typewriters		..	..	87	1,932	3,663
2. Glass-wares(breakage & discards)		..	..	..	..	4,018
3. Gas Charges		..	..	..	..	833
FACTORY ON-COST :	(b)	..	..	2.868	38,611	1,31,469
FACTORY COST :	(a) + (b)	..	..	2,868	57,360	2,35,295
GENERAL CHARGES						
1. Travelling Allowances		..	..	..	883	1,328
2. Electricity Charges		..	..	..	1,569	10,463
3. Water Charges		..	..	..	70	837
4. Misc. Charges		..	..	..	12,696	19,985
GENERAL ON-COST	(c)	..	..	..	15,218	32,613
TOTAL COST: (a)+(b)+(c)		..	..	2,868	72,578	2,67,908

Particulars	1965-66	1966-67	1967-68	1968-69 up to 9/68	Total
	Rs.	Rs.	Rs.	Rs.	Rs.
Chemicals Consumed . .	2,872	5,722	4,387	2,693	17,710
Establishment Charges (Pay & Allowances and C.P. Fund contributions) . .	1,14,189	1,24,790	1,42,508	69,953	5,62,141
Animals and their upkeep .	10,525	12,966	11,659	6,721	51,709
PRIME COST : (a)	1,27,586	1,43,478	1,58,554	79,367	6,31,560
1. DEPRECIATION CHARGES					
(i) Buildings . .	47,241	44,879	42,656	20,252	2,17,225
(ii) Plant & Machinery .	85,960	81,332	72,621	31,736	3,56,723
(iii) Scientific Apparatus & Laboratory equipments .	18,265	17,001	14,363	5,984	70,637
(iv) Furniture & Fitting and Typewriters . .	4,047	4,266	3,894	1,846	19,735
2. Glass-wares (breakage & discards)	7,726	12,429	18,969	6,772	45,914
3. Gas Charges .	922	863	1,359	279	4,256
FACTORY ON-COST : (b)	1,64,161	1,60,770	1,53,842	66,869	7,18,550
FACTORY COST: (a)+(b)	2,91,747	3,04,248	3,12,396	1,46,236	13,50,150
GENERAL CHARGES					
1. Travelling Allowance . .	2,359	1,671	338	2,796	9,375
2. Electricity Charges . .	17,430	20,689	23,515	12,584	86,250
3. Water Charges . . .	739	880	3,529	1,240	7,295
4. Msic. Charges . . .	24,424	24,395	12,430	4,494	98,424
GENERAL ON-COST (c) .	44,952	47,635	39,812	21,114	2,01,344
TOTAL COST: : (a)+(b)+(c)	3,36,699	3,51,883	3,52,208	1,67,350	15,51,494

Total cost of Bulk Stock of 1 millicn doses of Trivalent oral polio vaccine = Rs. 15,51,494

Cost per dose = Rs. 1·55

NOTE: --The cost works out above is exclusive of neurovirulence testing, bottling, labelling charges and packing, forwarding charges as also the contribution to be paid to the Pasteur institute, Coonoor and Departmental charges of the Medical Stores Depot, Madras.

11. COST SHEET IN RESPECT OF THE PRODUCTION OF 1.25 MILLION DOSES OF TRIVALENT ORAL POLIOVACCINE AT THE PASTEUR INSTITUTE OF SOUTHERN INDIA, COONOOR IN ONE YEAR

	Rs.	Rs.	Rs.
1. Cost of Chemicals	22,138		
2. ESTABLISHMENT CHARGES (Pay and Allowances and C.P. Fund contributions)	1,42,508		
3. Animals and their upkeep.	11,659		
PRIME COST (1 to 3):—		1,76,305(a)	
1. DEPRECIATION CHARGES.			
(i) Building	42,636		
(ii) Plant & Machinery	72,621		
(iii) Scientific Apparatus	14,363		
(iv) Furniture and Fittings and Typewriters.	3,894		
2. Glass-wares (Breakage & discards)	18,969		
3. Gas Charges	1,359		
FACTORY ON COST (1 to 3) :		1,53842(b)	
FACTORY COST (a)+(b) :			3,30,147(c)
GENERAL CHARGES			
1. Travelling Allowance.	338		
2. Electric Charges	23,515		
3. Water Charges	3,529		
4. Miscellaneous Charges	12,430		
GENERAL OVER-HEADS (1 to 4) :			39,812(d)
TOTAL COST OF BULK STOCK (c+d) (1.25 million doses of Trivalent vaccine)			3,69,959
	Paise		
Cost per dose.	29·6		
Add 10% for extra Vaccine bottled to cover loss in storage.	2.9		
TOTAL :	32·5		
Bottling and Labelling charges as pet separate sheet attached.	7·5		
TOTAL :	40.0		
Add 10% as estimated charges for Neurovirulence Test.	4.0		
TOTAL :	44·0		

	Paise
Add 2 Paise per dose to be given to Pasteur Institute, Coonoor as contribution.	2·0
Add 10% of cost (i.e. 44 Paise) as departmental charges of Medical Stores Depot, Madras.	4'0
TOTAL COST PER DOSE :	50.0

NOTE

The total cost of 50 paise per dose as worked out above is exclusive of packing and forwarding charges. it, however, includes a contribution of 2 paise per dose to be paid to Pasteur Institute, Coonoor and 10% departmental charges of the Medical Stores Depot, Madras, as per decision: mbodied in para 6 of the Minutes of the meeting of the Sub-Committee on the production, distribution, storage and supply of oral polivaccine held in Delhi on the qrd November, 1967. No interest on capital has been included in the cost as the exact amount of capital involved could not be ascertained in the absence of a proper Balance Sheet in respect of Polivaccine.

BOTTLING AND LABELLING CHARGES FOR 10 DOSES

	Paise
Cost of 10 dose (5 ml.) Vial	62·0
Cost of Rubber enclosure	2·8
Cost of Aluminium Seal	1·5
Cost of Polythene bags.	8·2
Cost of Label.	0·7
TOTAL :	75.2

	Paise.
Cost of bottling and Labelling per dose.	7·5

APPENDIX II

Summary of *Main Conclusions/Recommendations*

S. No.	Para No.	Ministry/Department concerned	Conclusion Recommendation
1	2	3	4
1	1.64	Ministry of Health and Family Planning (Department of Health)	The Committee are extremely dissatisfied with the performance and achievements of the polio vaccine production unit at the Pasteur Institute, Coonoor on which, as pointed out by Audit, Rs. 21.15 lakhs, excluding foreign aid of Rs. 7.48 lakhs, had been spent upto March 1972. They are concerned to note that as against its annual capacity of 12.50 lakh trivalent doses of vaccine, the unit has been able to produce only 4.61 lakh trivalent doses from December 1966 to May 1973, in a span of about 6½ years. The average annual production, thus, works out to only about 6 per cent of the capacity of the unit. Even conceding that the development of the vaccine is a sophisticated process and the production of contamination-free batches takes time, the present state of affairs at the Institute is far from satisfactory. The Committee apprehend that unless vigorous and concerted efforts are

2	1.65	do-

made to improve production and management techniques at the unit, the position may well become irretrievable.

In this context, the Committee are of the view that the assessments made by a senior official of the Indian Council of Medical Research and by a team of officers of the Council, the National Institute' of Communicable Diseases, Directorate General of Health Services and the Drug Controller, who had been deputed to conduct a detailed study of the shortfalls in production, are of considerable significance and merit serious and immediate attention. The picture that emerges from these two studies is far from complimentary both to the production unit and the Pasteur Institute. The following facts, in particular, bring out the sad state of affairs prevailing in the Institute:

(a) Lack of cooperation and support and a complete breakdown of human and personal relationships between the personnel of the production unit and the Director of the Institute;

(b) carelessness on the part of middle level supervisory staff in .coordinating the activities of the unit;

(t) absence of a long range plan of work, non-fixation of targets of production, non-assignment of responsibilities and the absence of frequent and regular checks;

(d) non-availability of trained middle level staff;

(e) a complete breakdown of the measures that would ensure sterility in the production chamber; and

(f) inadequate maintenance of equipment and records.

1	2	3
3	1.66	Ministry of Health and Family Planning (Department of Health)	The Committee attach considerable importance to the recommendation of the study team that the vaccine production unit should be placed under the overall charge of a wholetime officer who would be expected to deal with all the problems relating to premises, personnel, supplies and the production of vaccine. The Committee accordingly recommend that decision on this recommendation should be taken without further delay so as to place the production unit on a firmer footing.
4	1.67	-do-	The Committee learn that the present Director of the Pasteur Institute, who has vast experience in the field of polio vaccines will be available for only another two or three years. The problem of his replacement, when no longer available, calls for careful thought. It is, therefore, imperative that a sufficient number of persons are trained in the techniques and intricacies of production of polio vaccine so that production does not suffer in the years to come on account of the non-availability of suitable trained personnel. The Committee desire that urgent steps should be taken to impart necessary training to a sufficient number of middle-level staff who could effectively discharge the responsibility of overseeing the technical aspects of production.

5	1.68	-do-	In the opinion of the Committee, some of the technical problems brought to their notice during their examination are also not entirely insurmountable and are attributable more to negligence and carelessness. For instance, the Committee are surprised to learn that no attempt appears to have ever been made to check whether the germicidal lamps did possess, at a particular time on a particular day, any germicidal activity. Similarly, the electrical appliances are stated to be 'in a mess'. It is, therefore, obvious that effective supervision and prompt remedial measures have been inadequate, if not altogether non-existent. Since the techniral aspects of production imperatively call for constant scruinty, the Committee cannot countenance such lapses in the production of a sophisticated vaccine. They desire that responsibility should be fixed for the non-observance of even the basic, elementary requirements of successful production.
6	1.69	-do-	The Committee are of the view that the malady of the vaccine production unit at Coonoor is far more deep-seated than what meets the eye and the two studies emphasise the need for far-reaching changes and remedial measures. The Committee learn with consternation of the lack of cooperation and the complete breakdown of human and personal relationships at the institute and this should also cause great concern to Government. The Committee desire that the functioning of the unit should be comprehensively and expeditiously reviewed in the light of the analysis already made by the two study teams and urgent steps taken to remove the existing bottlenecks and obstacles and to streamline the production of the vaccine. The

1	2	3	4
			Committee note that a meeting had been held on 1st October 1974 to consider the recommendations of the Study Team and would like to be informed of the measures, if any, already taken in pursuance of these recommendations.
7	1.70	Ministry of Health and Family Planning (Department of Health)	It is also seen from the ICMR official's report that a team of experts from the World Health Organisation was scheduled to visit the Pasteur Institute at Coonoor in July 1974 to study the technical aspects of vaccine production. The Committee would like to be informed of the findings of this team and the action taken by Government on its recommendations.
8	1.71	-do-	The shortfall in production of the vaccine at the Pasteur Institute has also been attributed by the Director of the Institute to delays in the import of African green monkeys, chemicals and equipment. The Committee have been informed that while there was a delay of about six months in the issue of clearance by the Director General, Technical Development in respect of the import of 11 monkeys in 1970, necessary clearance had been issued by the Director General, Technical Development after 4 months in respect of a further import of 12 monkeys in 1973. The Committee are concerned over such delays in arranging imports of a vital pre-requisite for the production of the vaccine. The Committee are of the view that it should be possible to streamline the existing procedures for the issue of

			clearances by the Director General, Technical Development at least in respect of such imports by Central Government departments and organisations for which the justification is beyond doubt. The Committee desire that this should be examined and a suitable, simplified procedure evolved.
9	1.72	-do-	The Committee note that certain changes have been effected in the existing arrangements for sanctioning imports and the Ministry of Health has been empowered to sanction imports, up to an amount of Rs. 75,000, on their own judgment without referring the case to differentagencies. The Committee trust that with this arrangement, the bottlenecks in imports would be considerably eliminated. The Committee would like to be informed of the time now taken after the introduction of the revised procedure, for arranging imports of monkeys and other equipment etc. required by the Vaccine Production Unit.
10	1.73	-do-	The Committee desire that the possibility of breeding African green monkeys in India in a virusfree form, so as to reduce the dependence on imports, should be explored on a priority basis. The Committee take note of the assurance given by the Secretary, Ministry of Health and Family Planning during evidence that this suggestion would be pursued with the Veterinary Department and would like to be apprised of the progress made in this regard.

1	2	3	4
11	1.74	Ministry of Health and Family Planning (Department of Health)	The Committee have been informed that the production of vaccine is also liable to be affected by power failures and are surprised to learn that an automatic generator has not been installed so far. Since regular supply of power is one of the important factors for maintaining production of vaccine at an efficient level and its proper storage, the Committee desire that this deficiency should be made good on a priority basis.
12	1.75	-do-	The Committee are concerned to observe that the approval of the Drug Controller for the preparation of trivalent vaccine from the monovalent doses of vaccine produced at the Institute and tested in foreign countries had been communicated only 5 to 8 months after the receipt of test results. In the opinion of the Committee, this delay was by no means unavoidable. It is surprising that the circulation of the protocols by the Drug Controller to various agencies entrusted with the certification of the vaccine should have taken 5 to 8 months and the reasons advanced by the Ministry for this delay are not at all convincing. The Committee. however, note that the procedure has now been streamlined and that the certification by the Drug Controller would not take more than 2 to 3 weeks. The Committee trust that the revised schedule for the testing of the monovalent doses of the vaccine would be rigidly adhered to and prompt action taken to remedy the situation whenever delays of avoidable magnitude come to notice.

13	1.76	-do-	While the Committee can understand the reasons for the delays involved in the testing of the monovalent doses of vaccine in foreign countries, they are unable to appreciate the delays that have occurred at the testing division, established in the later part of 1970, in the National Institute of Communicable Diseases, New Delhi. The Committee find that the tests in respect of two batches of vaccine received in May, 1971 had been completed only after 11 months in one case and 14 months in another case. Though the time taken for the test has been reduced in respect of two subsequent batches received by the division in January 1973 and February 1974, the Committee are still unhappy with the performance of the testing division. The Committee would, therefore, like Government to investigate the reasons for the delay in testing the vaccine at the National Institute of Communicable Diseases and take suitable remedial measures to avoid recurrence of such delays, The Committee would like to be apprised of the action taken in this regard.
14	1.77	-do-	It is also a matter of concern to the Committee that the capacity of the testing division (on which, till March 1972, Rs. 14.45 lakhs had been spent, excluding cost of buildings) has been grossly under-utilised so far. The Committee note that only 25 lakh monovalent doses have been tested by the division till 1974 as against 19.2 crore monovalent doses that could have been tested. The under-utilisation of testing capacity has been mainly attributed to the existing limited capacity for productoin of the vaccine in the country and the delays in the

1	2	3	4
			receipt of batches for testing. However, even after streamlining the production at the Pasteur Institute so as to achieve the optimum capacity of 12.50 lakh trivalent doses, the percentage utilisation of the built-in capacity of the testing division would still be only about 15 per cent. The Committee are also doubtful whether, even after the establishment of another production unit at the Haffkine Institute, Bombay, it would be possible to utilise the full capacity of 160 lakh trivalent doses of the testing division. The Committee would like to be informed of the basis on which the existing capacity of the division has been worked out. Government should also examine immediately the feasibility of effecting economy in the expenditure on staff etc. of the testing division.
15	1.78	Ministry of Health and Family Planning (Department of Health)	It is also significant that while the cost of imported polio vaccine works out to only about 15 paise, the cost of production at the Institute is about 50 paise per dose. Considering the wide disparity in the cost of imported and indigenous vaccines, the Committee desire that urgent steps should be taken to reduce the cost of production by proved techniques. In this connection the Committee have been informed that an exercise in this regard had been carried out by a Cost Accounts Unit in 1968 and that the review of the cost of production at the Institute is under consideration of the Government. It is deplorable that no action has yet been initiated on the report of the Cost Accounts Unit, even after a lapse of more than six years. The Com-

			mittee take an extremely serious view of this delay and desire that responsibility should be fixed for the lapse and appropriate action taken under advice to them.
16	1.79	-do-	Now that the Haffkine Institute, Bombay is also expected to commence production of oral polio vaccine by the end of 1975, the Committee would like the economics of production and distribution of the vaccine at this Institute to be worked out in detail, in case this has not already been done, and intimated. The Committee also trust that the production at this Institute would be geared up and streamlined even in the initial stages in the light of the experience gained at the Pasteur Institute. The Committee expect that in this task there would be no lack of co-ordination, which appears to be feared, between the Institute, the Government of Maharashtra and also, of course, the Central Government. The Committee would be watching the performance of the Haffkine Institute with interest.
17	1.80	-do-	The Committee note that 1.71 lakh doses of polio vaccine supplied to the Medical Store Depot, Madras had remained unsold towards the closing months of 1974 and would like to be informed of the present position of sales at the depot.
18	1.81	-do-	The Committee And that on account of the delay in marketing the vaccine, the date of expiry of 0.60 lakh doses was over in July-August 1972 and consequently, these doses had to be retitrated and the period of their usability extended upto April 1975. The Committee would like to know the additional expenditure incurred in retitrating these doses and whether the entire quantity of 0.60 lakh doses has been

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			utilised, now that even the extended period is over. That such a measure was necessary would indicate the need for improving the facilities available for marketing the vaccine and apparently sufficient attention has not been paid to this important aspect. The Committee desire that the adequacy of the existing marketing arrangements should be reviewed and necessary remedial measures taken.
19	1.82	Ministry of Health and Family Planning (Department of Health)	The Committee are concerned to find that there has been no organised effort to rouse public awareness on anti-poliomyelitis in the rural areas. No national programme for immunisation against poliomyelitis has yet been contemplated though epidemics of polio have occurred in the country and relative to need, the efforts so far made are very limited and modest. The Committee consider it important that adequate measures are taken to educate the masses, particularly in the rural areas on polio and the efficacy of oral polio vaccine which Government should make every possible effort to provide in required quantity and quality. The Committee are of the view that the existing arrangements in this regard are far from adequate, and a more earnest and organised effort is called for. The Committee suggest that Government should, inter alia, utilise the powerful medium of films and radio so as to make a sustained impact on the rural population.

20	1.83	-do-	The Committee also find that it has been estimated that out of the population of 54.80 crores, according to the 1911 census, 8.20 crore children are in the susceptible group, for whom 24.60 crore doses of trivalent polio vaccine are needed annually, besides, for the estimated 1.30 crore new-borns, about 3.90 crore doses of trivalent vaccine are also required each year. Yet, the Committee are surprise to find that the country's annual requirement of polio vaccine has been presently estimated as only 1.20 crore trivalent doses. Apparently, the requirements have been placed at 1.20 crore doses as against the actual estimates of 28.50 crore doses on the basis of the expert view that the vaccine should be made available for immunisation for those who demand it and also used for transport entrusted. The number of doses actually available in the country (both imported and indigenously produced) has been much less than each this estimate. The authorities concerned seem to derive comfort from the fact that as the epidemic declines the public loss their enthusiasm for immunising the children and fail to give the three doses necessary to each child to ensure proper immunising in the opinion of the Committee this seems to suggest a certain complacence in regard to public indifference not unnatural in Indian conditions, towards serious health hazards. That such a situation has been allowed to persist only un-

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			derlines the urgent need to adequately educate the **public** on the dangers of polio and the measures to combat this acutely infectious disease.
21	1.84	Ministry of Health and Family Planning (Department of Health)	The Committee understand that while tap water is free from **the** virus of **poliomyelitis,** it is most dangerous to use water available from **hand-pumps.** While explaining the reasons for not **contemplating** a national programme **for immunisation** against polio, the Director General, Health Services had also stated that only by supplying protected water to the entire country, this disease can, to some extent be eradicated and that if this could be ensured, then there **would** be a national programme. The Committee would like to know the **concrete** steps taken by Government in this direction.

GMGIPND—LS II—962 LS— 5-8-75—1200.